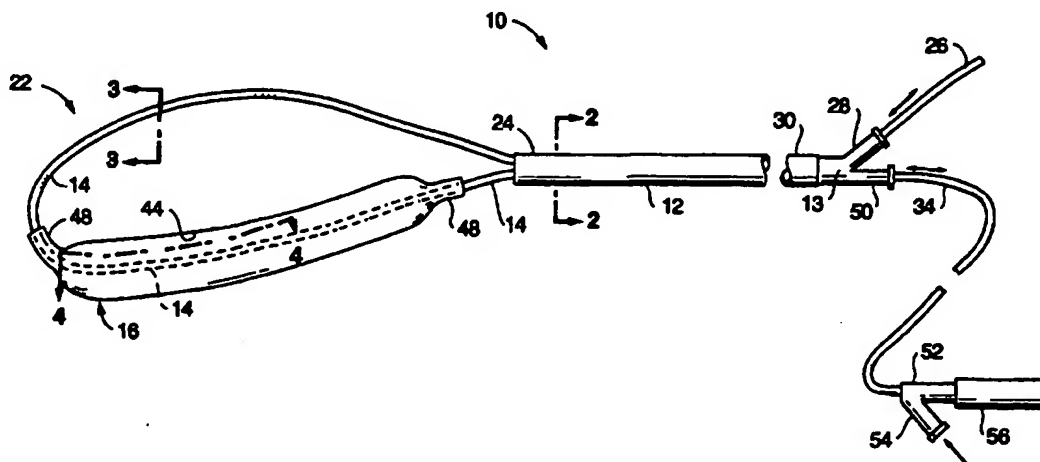




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(21) International Application Number: PCT/US96/17536 (22) International Filing Date: 4 November 1996 (04.11.96) (30) Priority Data: 08/611,656 6 March 1996 (06.03.96) US (71) Applicant: CARDIAC PATHWAYS CORPORATION [US/US]; 995 Benecia Avenue, Sunnyvale, CA 94086 (US). (72) Inventors: POMERANZ, Mark, L.; 110 Ann Arbor Court, Los Gatos, CA 95032 (US). CHAPMAN, Troy, J.; 10490 Cypress Drive, Cupertino, CA 94014 (US). SHERMAN, Darren, R.; 746 Brentwood Drive, San Jose, CA 95129 (US). IMRAN, Mir; 26641 Laurel Lane, Los Altos Hills, CA 94022 (US). (74) Agents: STALLMAN, Michael, A. et al.; Limbach & Limbach L.L.P., 2001 Ferry Building, San Francisco, CA 94111 (US).		(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report. With amended claims.

(54) Title: APPARATUS FOR CREATING LINEAR LESIONS BY ABLATION



## (57) Abstract

An apparatus for ablating body tissue, and particularly for creating linear lesions within a chamber of a patient's heart, includes an elongate member having an ablation section. The ablation section includes an infusion tube and a plurality of spaced electrodes. The infusion tube and electrodes are covered by a fluid permeable foam material, and the foam material is covered by a fluid impermeable covering having a plurality of holes formed in it. During use, the ablation section is positioned against tissue to be ablated. Radiofrequency energy is delivered to the electrodes while saline or other conductive fluid is delivered to the infusion tube. The fluid exits the infusion tube at the ablation section, contacts the electrodes, and carries RF energy from the electrodes through the foam, through the holes in the covering and into contact with the body tissue to form a burn in the body tissue.

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## APPARATUS FOR CREATING LINEAR LESIONS BY ABLATION

Field of the Invention

5           The present invention relates generally to the field of apparatuses and methods for ablating living tissue. In particular, the present invention relates to the field of devices and methods for creating  
10       lesions within the heart.

Background of the Invention

          Atrial fibrillation is a condition in the heart in which abnormal electrical signals are generated in  
15       the endocardial tissue to cause irregular beating of the heart. One method used to treat atrial fibrillation involves creating several long (i.e. approximately 2-10 cm) lesions on the endocardium within the atria. These lesions are intended to stop  
20       the irregular beating of the heart by creating barriers between regions of the atria. These barriers halt the passage through the heart of the abnormal currents generated by the endocardium. This procedure is commonly referred to as the "maze  
25       procedure" because it creates a maze of lesions design to block the passage of abnormal currents through the heart.

          Existing procedures for forming such linear lesions include the highly invasive technique of  
30       opening the patient's chest and heart and forming linear incisions inside the atria. Naturally, the highly invasive nature of this procedure makes it a particularly high risk to the patient and necessitates extraordinarily long recovery time.

35       Other attempts have been made to form the linear lesions using ablation catheters fed into the heart via the patient's vessels (i.e., the arteries or veins). For example, one such procedure involves

inserting into the atria a 7 French catheter having an ablation tip. Radio frequency (RF) energy is supplied to the tip as the tip is dragged across the endocardium, thereby burning linear lesions into the endocardium.

While often successful for forming linear lesions, the ablation tip of the catheter can sometimes lift off of the surface of the endocardium as it is dragged across the endocardium, creating one or more breaks in the lesion. Such breaks minimize the success of the ablation procedure by leaving a path through which current may travel during atrial fibrillation episodes.

Another type of existing RF linear lesion catheter has a plurality of spaced ring electrodes encircling the distal end of the catheter. Although ablation using such catheters has been successful, a large spacing (i.e. on the order of greater than 4 mm) must be provided between the ring electrodes to give the catheter adequate flexibility to move through the vessels and the heart. Unfortunately, however, leaving large spaces between the electrodes may prevent RF energy from being focussed at certain points along the catheter and may thereby produce regions in the linear lesion which are not sufficiently necrosed to prevent the passage of current during atrial fibrillation episodes. Additionally, blood may coagulate on the surface of the metal ring electrodes, which can prevent RF energy from reaching the endocardial tissue. Coagulum on the surface of the electrodes may present a safety hazard in that it may eventually fall off the electrode and into the patient's bloodstream, causing an embolic event.

Procedures and devices for forming linear lesions within the atria are therefore desired which

will block the passage of current through the heart during atrial fibrillation episodes, as with the surgical incision procedure, but which utilize the less-invasive technique of a percutaneous catheter. Further desirable is a linear lesion catheter having the flexibility and maneuverability of the electrode tipped catheter but which generates a continuous lesion on the endocardium.

It is further desirable to improve the continuity and thus the effectiveness of linear lesions formed using ablation catheters by providing means by which a linear lesion catheter may be held securely against endocardial tissue during ablation, and by which electrical energy may be focussed from the ablation electrodes onto the endocardium.

#### Summary of the Invention

The present invention is a catheter device for creating linear lesions in endocardial tissue or other body tissue. The catheter includes an elongate member having an ablation section at which a number of spaced apart electrodes are carried. An infusion tube is also carried by the elongate member. The infusion tube has a plurality of tiny holes positioned near the electrodes.

During use, the ablation section of the apparatus is positioned adjacent to the body tissue which is to be ablated. RF energy is delivered to the electrodes while saline or other conductive fluid is simultaneously delivered through the infusion tube. The conductive fluid passes out of the openings in the infusion tube and contacts the electrodes. The fluid also flows into contact with the body tissue, thereby improving the coupling of the RF energy from the electrodes to the tissue and improving the efficiency of the ablation of the tissue.

Utilizing a conductive liquid which is dispersed over the desired area as a mechanism for coupling RF energy to the tissue produces lesions having greater continuity (and thus fewer breaks through which current can pass during atrial fibrillation episodes) than lesions formed by prior art apparatus which rely solely on direct contact between the electrodes and the body tissue. The conductive liquid also cools the electrodes, decreasing the likelihood of thrombus formation on the electrodes and thus decreasing the chance of embolism.

In preferred embodiments, delivery of current to the tissue is further improved by surrounding the electrodes with foam material and by covering the foam with a substantially fluid impermeable covering having a number of tiny holes formed in it. Saline (or another conductive medium) flowing into the foam is uniformly dispersed within it, and then is focussed onto the body tissue as it passes through the holes in the covering.

Because the foam is deformable, it conforms the covering to the surface of the body tissue when the ablation section is positioned in contact with body tissue. Further, as saline infuses into the foam, it slightly expands the covering against the tissue thereby providing positive pressure between the covering and the body tissue. Certain of the embodiments are further provided with baffle wires that mechanically leverage the ablation section against the body tissue which is to be ablated by pushing against opposing body tissue. In such embodiments, the ablation section may be fixed or slidable on the baffle wire.

Brief Descriptions of the Drawings

Fig. 1 is a side elevation view of a first embodiment of a linear lesion catheter according to the present invention.

5 Fig. 2 is a cross-section view of the main shaft of the linear lesion catheter of Fig. 1, taken along the plane designated 2-2 in Fig. 1.

Fig. 3 is a cross-section view of the baffle wire of the linear lesion catheter of Fig. 1, taken along the plane designated 3-3 in Fig. 1.

10 Fig. 4 is a cross-section view of the ablation section of the linear lesion catheter of Fig. 1, taken along the plane designated 4-4 in Fig. 1.

Fig. 5 is a cross-section view of the ablation section of the linear lesion catheter of Fig. 1, taken along the plane designated 5-5 in Fig. 4.

15 Figs. 6A through 6D are a series of side elevation views of the linear lesion catheter of Fig. 1 illustrating operation of the device.

Fig. 7 is a side elevation view of a second embodiment of a linear lesion catheter according to the present invention.

Fig. 8A is a cross-section view of a proximal portion of the tubing of the catheter of Fig. 7, taken along the plane designated 8A-8A in Fig. 7.

25 Fig. 8B is a cross-section view of a proximal portion of the tubing of the catheter of Fig. 7, taken along the plane designated 8B-8B in Fig. 7.

Fig. 8C is a cross-section view of the baffle wire of the catheter of Fig. 7, taken along the plane designated 8C-8C in Fig. 7.

30 Fig. 9 is a cross-section view of the ablation section of the catheter of Fig. 7, taken along the plane designated 9-9 in Fig. 7.

Fig. 10 is a cross-section view of the ablation section of the catheter of Fig. 7, taken along the plane designated 10-10 in Fig. 9.

Figs. 11A through 11D are a series of side elevation views of the linear lesion catheter of Fig. 7 illustrating operation of the device.

5 Figs. 12A through 12C show a catheter which is similar to the catheter of Fig. 7 but which utilizes and an alternative tubing configuration. Fig. 12A is a side view of the alternative catheter.

10 Fig. 12B is a cross-section view of a distal portion of the alternative catheter taken along the plane designed 12B-12B in Fig. 12A.

Fig. 12C is a cross-section view of a proximal portion of the alternative catheter taken along the plane designed 12C-12C in Fig. 12A.

15 Fig. 12D is a cross-section view of the ablation section of the alternative catheter taken along the plane designed 12D-12D in Fig. 12A.

Fig. 12E is a cross-section view of the ablation of Fig. 12D, taken along the plane designated 12E-12E in Fig. 12D.

20 Fig. 13A is a side elevation view of a third embodiment of a linear lesion catheter according to the present invention.

Fig. 13B is a cross-sectional side view of a distal section of the catheter of Fig. 13A.

25 Fig. 13C is a side elevation view of a portion of the catheter of Fig. 13A illustrating the manner in which the catheter secures the ablation section against endocardial tissue.

30 Fig. 14A is a side elevation view of a fourth embodiment of a linear lesion catheter according to the present invention.

Fig. 14B is a cross-sectional side view of a distal section of the catheter of Fig. 14A.

35 Fig. 14C is a side elevation view of a portion of the catheter of Fig. 14A illustrating the manner



in which the catheter secures the ablation section against endocardial tissue.

5 Fig. 15A is a cross-sectional side view of a fifth embodiment of a linear lesion catheter according to the present invention.

Fig. 15B is a side plan view of an embodiment similar to the embodiment of Fig. 15A, in which each of the foam segments is provided with a separate covering.

10 Fig. 16 is a cross-sectional side view of a sixth embodiment of a linear lesion catheter according to the present invention which is similar to the fifth embodiment but in which the foam support structure of the fifth embodiment has been replaced  
15 by inflatable support structures.

Fig. 17 is a cross-sectional side view of a seventh embodiment of a linear lesion catheter according to the present invention which is similar  
20 to the fifth embodiment but in which the foam support structure and covering have been removed.

#### Detailed Description of Exemplary Embodiments

25 A first embodiment of a linear lesion catheter 10 according to the present invention is shown in Fig. 1. The catheter 10 is comprised generally of a main shaft 12, a looped baffle wire 14 which extends through the main shaft 12 and which is extendable out  
30 of the distal end of the main shaft 12, and an ablation section 16 formed on the baffle wire 14. During use, the ablation section 16 is positioned against the target tissue to be ablated and which delivers RF energy to the tissue to cause ablation.  
35 It should be appreciated that other types of ablation elements may be substituted for the RF ablation

elements described in this and the following  
embodiments. For example, ultrasound ablation  
elements or other conventional ablation tips may be  
used in combination with some or all of the other  
features of the invention described herein without  
departing from the scope of the present invention.

Referring to Fig. 2, main shaft 12 is an  
elongate shaft having a pair of lumens 18a, 18b  
extending from its proximal to its distal end.

Although the main shaft 12 is substantially straight  
in this and the other embodiments described herein,  
it may alternatively have a curved profile at its  
distal end to facilitate contact between it and the  
target tissue to be ablated. Main shaft is  
preferably constructed of a thermoplastic polymer,  
polyamid ether, polyurethane or other material having  
similar properties. A stainless steel braid (not  
shown) is preferably embedded in the wall of the main  
shaft by means conventionally known in the art. The  
inclusion of the braid improves the torque  
characteristics of the main shaft 12 and thus makes  
the main shaft easier to maneuver through patient's  
vessels and heart. A connector 13 is attached to the  
proximal end of main shaft 12.

Referring to Fig. 3, baffle wire 14 is an  
elongate length a metallic core wire 20 encased in  
thin shrink tubing 21 or other flexible tubing such  
as polyolefin, thermoplastic polymer, polyamid ether  
(nylon), silicone, or polyurethane. Metallic core  
wire 20 extends the length of the shaft and may be  
formed of, for example, stainless steel or shape  
memory metal such as Nitinol. The baffle wire 14 may  
alternatively be formed of a more rigid material such  
as conventional braid tubing, in which case the core  
wire 20 may be eliminated.

Baffle wire 14 extends through each of the lumen 18a, 18b in the main shaft 12 and forms a loop 22 (Fig. 1) adjacent to distal end 24 of the main shaft 12. Baffle wire 14 includes a first end 26 which  
5 extends from a port 28 in connector 13. A second end 32 of baffle wire 14 lies within tubing 34 which extends from proximal end 30 of the main shaft and which will be described in detail below.

Ablation section 16 of the catheter 10 is shown  
10 in cross-section view in Figs. 4 and 5. Referring to Fig. 5, ablation section 16 includes a small diameter (i.e., approximately 0.5 mm dia.) fluid infusion tube 36 which extends adjacently to a portion of baffle wire 14. Infusion tube 36 includes a sealed distal  
15 end 37 and it extends proximally through the main shaft 12 and the tubing 34. A plurality of spaced holes 38 extend along the portion of the infusion tube 36 which lies at the ablation section 16.

A plurality of lead wires 39 (Fig. 5), which are  
20 preferably formed of copper, extend adjacently to the infusion tube 36 and the baffle wire 14. Referring to Fig. 4, each lead wire 39 has a distal end coiled around the infusion tube 36, baffle wire 14, and other lead wires 39 to form a coil electrode 40. The  
25 proximal portions of the lead wires 39 extend through the main shaft 12 and tubing 34 and are coupled to an electrical adapter as will be described below. The portions of the lead wires 39 which are disposed within the ablation section 16 are not insulated from  
30 one another, while the portions of the lead wires 39 which lie within the main shaft 12 and tubing 34 are preferably insulated from one another by shrink tubing or other means.

Other types of electrodes may alternatively be  
35 used in this and the other embodiments described herein. For example, ring electrodes may be

utilized, or spaced conductive strips or bands may be formed on the surface of the baffle wire, or wire braids or other conductive material may be helically wound around the baffle shaft. The electrodes may also be formed from conductive wires or ribbons, each of which is covered by an insulated coating. An example of such wires (in an uncoiled form) is designated 94a in Fig. 12D and is described in the description accompanying Fig. 12D. The wire 94a is an 0.005 " diameter wire which is provided with exposed electrode regions 96a that are stripped of insulative material. Such flattened wires or ribbons may be advantageous in that they produce RF energy electric field lines which are not concentrated at the edges of the ribbons, but are instead dispersed along the entire length of the ribbon.

Deformable members, or foam support segments 42 surround the electrodes 40. These segments 42 are formed of open cell polyurethane, cotton-like material, open-cell sponge, hydrogels, or other foam-like materials or materials which are permeable by conductive fluids and which exhibit some compressibility. The deformable member need not be segmented but it has been found that RF energy is more effectively channeled to the cardiac tissue by providing the foam in segments rather than in a continuous piece.

The support segments 42 are preferably foam tubes which during manufacture are slipped over the baffle wire 14 into position over the electrodes. Alternatively, foam sheets may be wrapped around the electrodes to form tubes around the electrodes, and the overlapping sides of each sheet glued together to maintain each sheet in a tubular configuration.

The support segments 42 are enclosed within a covering 44 formed of heat shrink polyethylene,

silicone, or other polymeric materials having a plurality of small holes 46 or perforations formed in it. The covering 44 is preferably held in place by heating ends 48 (Fig. 1) of the covering to cause the heat shrink material to melt onto the baffle wire 14. Covering 44 may also be a dip coating formed on the foam surface.

A number of functions are performed by the foam 42 and covering 44 during use of the device. During use, the ablation section 16 of the device is positioned in contact with the region of the endocardium which is to be ablated. The foam provides structural support for the covering and facilitates contact between the covering and endocardial surface by compensating for features on the endocardial surface which are not smooth. It should therefore be appreciated that in this and the below described embodiments, the foam support segments may be replaced by other mechanical means which give structure integrity to the covering 44. For example, inflatable balloons may be positioned within the covering and inflated to push the covering outwardly against the endocardial surface. Alternatively, the covering may be positioned over plastic or metallic spring structures.

Further, as described in detail below, RF energy is delivered to the endocardium by a conductive path through the saline which flows through the foam and out of the covering onto the endocardium. The foam 42 helps the saline to flow evenly through and out of the covering and therefore facilitates transmission of RF energy to the endocardium.

The plurality of tiny holes 46 formed in the covering 44 serve as the conduit through which saline passes from the foam to the endocardium. The fluid flow through the holes focuses the RF energy onto the

tissue. The pattern in which the holes are arranged is selected to insure infusion of saline and delivery of RF energy to the underlying tissue even if the ablation section 16 should rotate during use. The distribution of holes formed in the covering should be limited to that which will create a continuous transmural linear lesion over the desired ablation surface. It has been found desirable to use four rows of 0.007" diameter holes spaced 1.0 mm apart over the length of the active region of the ablation section, to give approximately 40 such holes per centimeter over the active region. Six rows of holes (or 60 holes per centimeter) is also believed to give good results.

It may also be desirable to arrange the holes so that they extend only along one side of the covering (i.e., the side which, during use, will be positioned against the target ablation site) in order to prevent RF energy from being lost into the blood pool. See, for example, holes 110a in Fig. 12D. It should be appreciated, however, that many hole sizes and patterns may be utilized without departing from the scope of the present invention.

The covering 44 helps to prevent blood from entering the ablation section, and the positive outward flow of saline from the covering reduces the likelihood of thrombus buildup at the ablation site.

Referring to Fig. 1, tubing 34 (which, as shown in Fig. 2, contains baffle wire 14, leads 39, and infusion tube 36 within it) extends through the main shaft 12 from the proximal end 24 of the main shaft, and it exits distal end 30 of main shaft via a port 50 in connector 13. Tubing 34 is slidably disposed within main shaft 12 and connector 13.

Tubing 34 is joined at its proximal end to a second connector 52. Tubing 34 terminates at

connector 52, and the infusion tube 36 and lead wires 39 which are within it (see Fig. 2) diverge from one another such that infusion tube 36 is fluidly coupled with a fluid port 54 in connector 52 and such that lead wires 39 are electrically coupled to a female adapter 56. The portion of baffle wire 14 located at connector 52 does not extend into the fluid port 54 or the female adapter 56 but instead terminates at, and is fixed within, connector 52.

Female adapter 56 is preferably configured to be coupled to a multi prong male adapter 58 (Fig. 6A) which is electrically coupled to a conventional RF generator (designated 60 in Fig. 6A) such as Model 8002 RF Generator which is available from Cardiac Pathways Corporation, Sunnyvale, California. Each lead wire 39 coupled to the female adapter preferably terminates in a socket which is separate from the other sockets in the female adapter and which is configured to mate with a corresponding prong of the male adapter. Thus, for example, if the linear-lesion catheter is provided with six electrodes 40 (Fig. 2), there will be six leads 39, each extending from one of the electrodes 40, and there will be at least six sockets in the female adapter which correspond to six prongs in the male adapter.

Operation of the first embodiment 10 of a linear lesion ablation catheter 10 according to the present invention will next be described. Prior to beginning the procedure, tubing 34 and end 26 of baffle wire 14 are pulled in a proximal direction, as indicated by arrows in Fig. 6A, to withdraw the loop 22 inside distal end 24 of main shaft 12. Female adapter 56 is connected to a male adapter 58 which is coupled to a source 60 of RF energy. A conventional grounding

patch or other grounding device is attached to the patient's body.

5 With the loop 22 inside main shaft 12, main shaft 12 is threaded through a patient's vessels and into the heart using conventional techniques. Once  
10 distal end 24 of main shaft 12 is positioned within the appropriate chamber of the heart, end 26 of baffle wire 14 and/or the tubing 34 is advanced distally to push the loop 22 out of distal end 24 of  
15 main shaft 12 (Fig. 6B). The height, location and size of the loop 22 may be adjusted to position the ablation section 16 of the apparatus against the desired surface within the heart chamber and to maintain contact between the ablation surface of the  
catheter and the target surface within the heart chamber. These adjustments can be made by moving end 26 and/or tubing 34 distally or proximally as needed, and also by rotating the main shaft 12.

20 For example, tubing 34 may be moved distally to advance ablation section 16 and to thereby increase its curvature as shown in Fig. 6C, if such curvature will conform the ablation section 16 to the cardiac tissue T.

25 Moreover, loop 22 is preferably positioned within the heart such that ablation section 16 is leveraged against a chamber wall W1 by the action of the opposite side of the loop 22 against an opposing chamber wall W2 as in Fig. 6D. Pressing the ablation  
30 section 16 against the endocardium in this manner helps the ablation section to conform to the surface of the endocardium and thus helps ensure that sufficient contact is made between the ablation section and the endocardium. Good contact between the ablation section and the underlying tissue is  
35 essential to the creation of a continuous transmural lesion.



Delivery of RF energy to the endocardial tissue is commenced once ablation section 16 is in contact with the desired region of the endocardial surface. RF energy from RF generator 60 is delivered to electrodes 40 via leads 39. At the same time, conductive fluid, such as saline S (Fig. 6A), is directed into port 54 and through infusion tube 36. It may also be desirable to begin to begin to apply positive fluid pressure even before RF ablation is commenced, in order to prevent blood accumulation in or on the covering.

The saline passes through holes 38 in the infusion tube 36, then through the foam 42, and out of the covering 44 via holes 46. As the saline moves from the holes 38 to the exterior of the covering, it creates a conductive path (for passage of the RF energy) between the electrodes and the endocardium (see arrows in Fig. 6D). The RF energy travels along this conductive path from the electrodes, through the foam and the holes in the covering, and then into the tissue. Once a lesion has been formed at the target spot, the catheter 62 may be repositioned within the selected chamber of the heart and additional lesions formed.

Although it is preferred to utilize the conductive fluid or saline in a manner in which the conductive fluid creates a conductive path between the electrodes and the target tissue, saline may alternatively or additionally be utilized in the present invention to cool the ablation electrodes.

A second embodiment of a linear lesion catheter 62 is shown in Figs. 7 - 11B. Like the first embodiment, in the second embodiment the ablation section is positioned on a baffle loop at the distal end of the apparatus. The second embodiment differs

from the first, however, in that in the second embodiment the ablation section is slidable over the baffle wire. Thus, once the catheter has been inserted into a heart chamber and the loop has been formed to a desired size, the position of the ablation section on the loop may be adjusted to position the ablation section at the target ablation location.

Catheter 62 generally includes a main shaft 64, a baffle ribbon 66 which has one end fixed to the distal end of the main shaft 64 and another end extending through main shaft 64, and an ablation section 68 slidably received on the baffle ribbon 66. The ablation section 68 preferably has a length of approximately 2 - 10 cm and an outer diameter of approximately 3 - 5 mm.

Referring to Fig. 7, main shaft 64 includes a distal end 70 and a proximal end 72. The main shaft 64 is preferably a single lumen length of tubing constructed of a thermoplastic polymer, polyamid ether, polyurethane or other material having similar properties. The diameter of main shaft 64 is preferably approximately 9 - 11 French (approximately 3 - 4 mm). A stainless steel braid (not shown) is preferably embedded in the wall of the main shaft by means conventionally known in the art. The inclusion of the braid improves the torque characteristics of the main shaft 64 and thus makes the main shaft easier to maneuver through a patient's vessels and heart. A Teflon® lining (not shown), also conventional in the art, preferably lines the interior wall of the main shaft 64 to cover the wire braid. To minimize tissue trauma as the main shaft 64 is fed through a patient's vessels and heart during use, the braid is preferably absent from the first several centimeters at the distal tip 71 of the

main shaft. This leaves the tip 71 sufficiently flexible to yield when advanced against obstacles within the vessels and heart.

5 Referring to Figs. 7, 8A and 8B, tubing 74, which is preferably made of a thick walled heat shrink tubing or thermoplastic polymer, is slidably received within main shaft 64 and is extendable from the distal end and proximal ends 70, 72 of the main shaft 64. A connector 76 is attached to the proximal  
10 end of tubing 74.

Baffle ribbon 66 extends through a lumen 78 in the tubing 74 and is preferably covered with a Teflon® coating. As shown, baffle ribbon 66 preferably has a substantially flat cross-section  
15 (i.e., rectangular or oblong). This prevents the baffle ribbon 66 from rotating about its longitudinal axis during use.

Baffle ribbon 66 has a distal end 80 which is secured to the distal end 70 of main shaft 64 as  
20 shown in Fig. 7. Baffle ribbon 66 extends through the ablation section 68 of the device as will be described below, enters the distal most portion of tubing 74 (see Fig. 8A), and extends through the entire length of the tubing 74 (see Fig. 8B). It  
25 further extends through connector 76 attached to the proximal most end of the tubing 74 and extends freely out of an opening in the proximal most end 80 of the connector (see Fig. 7).

Referring to Fig. 9, an infusion tube 82 extends  
30 through the ablation section 68 and through the tubing 74. Infusion tube 82 includes a sealed distal end 84 and a proximal end 88 fluidly coupled with a fluid port 90 formed in connector 76. A plurality of spaced holes 92 extend through the portion of the  
35 infusion tube 82 positioned at the ablation section 68 of the device.

A plurality of lead wires 94 (Figs. 8A, 8B and 10), which are preferably formed of copper, extend through ablation section 68 and further extend through tubing 74, adjacent to the infusion tube 82. As can be seen in Fig. 10, at the ablation section 68 of the apparatus the lead wires 94, infusion tube 82, and the lumen that baffle ribbon 66 rides in are encased in thin walled polyethylene heat shrink tubing 98 (not visible in Fig. 9). Each lead wire 94 has a distal end which pokes through the shrink tubing 98 and is coiled to form a coil electrode 96 around the shrink tubing 98 and thus the infusion tube 82, the baffle ribbon 66, and the lead wires which are within it (see Fig. 10). Each of the wires 94 passes through the shrink tubing 98 at a different point along the length of the ablation section 68 such that the electrode coils 96 are spaced from one another. The proximal portions of the lead wires 94 pass through the tubing 74 and are electrically coupled to a female adapter 100 as described with respect to the first embodiment. The portions of the lead wires 94 which are disposed within the ablation section 68 are not insulated from one another, while the portions of the lead wires 94 which lie within the tubing 74 are preferably insulated from one another by shrink tubing or other means.

As can be seen in Figs. 8A and 8B, the portions of the infusion tube 82 and lead wires 94 which are disposed within the tubing 74 are bundled together using thin walled polyethylene heat shrink tubing 102, whereas the portion of the baffle ribbon 66 lying within the tubing 74 is preferably not bundled within the tubing 102. A stiffening wire 104 extends through a proximal portion of the tubing 74 to facilitate manipulation of the catheter 62 within a patient's vessels and heart. Stiffening tube 104 has

a proximal end (not shown) which is secured to connector 76, and an unsecured distal end (not shown) located proximally of distal tip 71 of main shaft 64 (compare Figs. 8A and 8B).

5 Referring again to Figs. 8A, 8B and 10, it can be seen that the same shrink tubing 98 which, at the ablation portion 68 (Fig. 10) of the device, encloses the leads 94, the lumen 78 within which the baffle ribbon 66 rides, and fluid lumen 82 also encloses  
10 tubing 102 (including infusion tube 82 and lead wires 94 which are within it), the lumen 78 within which the baffle ribbon 66 rides, and the stiffening wire 104 which are enclosed within the tubing 74. Moreover, it should be understood that during  
15 manufacture the thick walled tubing 74 becomes melted onto the underlying tubing 98 and thus prevents sliding of the shrink tubing 98 within the tubing 74.

Referring to Figs. 9 and 10, support segments  
20 106 formed of open cell polyurethane or other foam material are positioned to surround the electrode coils 96. The foam need not be segmented but as described below it has been found that RF energy is more effectively channeled to the cardiac tissue by providing the foam in segments. As described with  
25 respect to the first embodiment, the support segments 106 are preferably foam tubes which during manufacture are slipped over the baffle ribbon 66 and into position over the electrodes.

The support segments 106 are enclosed within a  
30 covering 108 formed of heat shrink polyethylene or other polymeric material and preferably held in place by melting the distal and proximal ends of the covering onto the underlying structures.

35 A plurality of tiny holes 110 are formed in the covering 108 and serve as the conduit through which saline passes from the foam to the endocardium. The

pattern in which the holes are arranged is thus selected to insure infusion of saline and deliverance of RF energy to the underlying tissue even if the ablation section 68 should rotate during use.

5 Because the holes focus the RF energy onto the tissue, it is preferable to limit the number of holes formed in the covering to that which will create a continuous transmural linear lesion.

10 Operation of the preferred catheter 62 according to the present invention will next be described. Prior to beginning the procedure, baffle ribbon 66 is pulled in a proximal direction to withdraw its distal portion as well as the ablation section 68 inside distal end 70 of main shaft 64. See Fig. 6A.

15 Female adapter 100 is connected to a male adapter which is coupled to a source of RF energy as described above with respect to the first embodiment.

Once the ablation section 68 and the distal portion of the baffle ribbon 66 are inside main shaft 64, the main shaft 64 is threaded via a patient's vessels (one of which is designated A in Fig. 11A) into the heart using conventional techniques. Once distal end 70 of main shaft 64 is positioned within the appropriate chamber of the heart, the proximal end of baffle ribbon 66 is advanced distally as shown in Fig. 11B. Because distal end 80 of baffle ribbon 66 is fixed to the main shaft 64, distal movement of the baffle ribbon causes it to form a loop 112 with itself. Additional distal movement of the baffle ribbon 66 increases the size of the loop 112 as shown in Fig. 11C. Deployment of the baffle ribbon 66 continues until the loop 112 is of sufficient size that it fills the heart chamber (i.e., such that both ablation section 68 and the side of the loop 112 opposing the ablation section are in contact with opposition regions T1 and T2 of endocardial tissue).

Next, the position of the ablation section 68 along the baffle wire 66 may be adjusted by sliding tubing 74 in a proximal or distal direction (distal sliding is indicated in Fig. 11D), to cause tubing 74 and thus inner shrink tube 98, to slide. Because the baffle ribbon 66 is not secured within the tubing 74 and 98, the tubing 74, 98 and the elements encased within it (i.e. the infusion tube 82 and the lead wires 94) slide over the baffle ribbon 66 while the baffle ribbon remains in place.

As described with respect to the first embodiment, delivery of RF energy to the endocardial tissue is commenced once ablation section 68 has been positioned in contact with the desired region of the endocardial surface. RF energy from an RF generator is delivered to the coil electrodes 96 via leads 94 and is carried from the electrodes 96 to the endocardium by a conductive fluid, such as saline S (Fig. 11D). As with the previous embodiment, the saline is directed into infusion tube 82 (Fig. 10) by fluid port 90. The saline passes through the holes 92 in the lumen 36, and then through the support segments 106, and it subsequently travels out of the covering 108 via holes 110. As the saline moves from the holes 110 to the exterior of the covering, it carries the RF energy passed from the electrodes through the foam out of the covering and onto the endocardium. Once a lesion has been formed at the desired spot, the user may reposition the ablation section 68 by sliding it proximally or distally over the baffle wire 66 (with or without first repositioning the baffle wire 600 within the chamber of the heart) in order to position the ablation section for formation of additional lesions. Once the ablation section is repositioned, RF energy is delivered to the electrodes to form additional

lesions or to increase the length of the previously formed lesion.

Figs. 12A - 12C show an alternative catheter according to the present invention. This is  
5 embodiment is like the embodiment of Fig. 7 in that the ablation section 68a is slidable over a baffle wire, but it differs primarily with respect to the configuration of the tubing 74a which extends through the shaft 64.

10 Figs. 12D and 12E are cross-section views of the ablation section 68a and illustrate the differences between the tubing 74a and the tubing 74 of the embodiment of Fig. 7.

15 Fig. 12B shows the distal portion of the alternative tubing 74a. Tubing 74a is a five lumen tubing which obviates the need for the various other tubing (e.g., such as tubing 102 and 98) utilized in the embodiment shown in Figs. 8A and 8B. Elimination of tubing makes it easier to construct the catheter  
20 to have a small diameter. Thus, it may be desirable to utilize multi-lumen of this type in the first and second embodiments or in any embodiments of the device according to the present invention.

25 Tubing 74a includes preferably four fluid lumen 82a and a baffle lumen 67 which extend throughout its proximal (Fig. 21C) and distal (Fig. 12B) sections. Lead wires 94a extend through the fluid lumen 82a. Each of four fluid ports 88a - 88d (Fig. 12A) is fluidly coupled to one of the fluid lumen 82a at the  
30 proximal end of the tubing 74a.

Baffle ribbon 66a extends through a baffle ribbon lumen 67 in the tubing 74a. Baffle ribbon lumen 67 is preferably oblong shaped to prevent rotation of the baffle ribbon 66a within it.

35 Referring to the proximal portion of tubing 74a shown in Fig. 12C, the proximal section tubing 74a



includes the fluid lumen 82a and the baffle ribbon lumen 67 described above, and it also includes preferably two stiffening wire lumen 105. Thus, there are five lumen extending through the distal portion (Fig. 12B) of the tubing 74a and there are seven lumen extending through the proximal portion (Fig. 12C). The seven lumen proximal portion of the tubing 74a and the five lumen distal portion are fused together by conventional means.

Referring again to Fig. 12C, stiffening wires 104a extend through stiffening wire lumen 105 and thereby enhance the stiffness of the proximal portion of the catheter.

Figs. 12D and 12E show the alternative ablation section 68a which utilizes the tubing 74a. Ablation section 68a is provided with foam segments or a foam layer, designated 106a, which is formed in an eccentric configuration such that it is thicker on one side of the ablation section 68a than it is on the other side. During use, the side of the ablation section having the thick region of foam is positioned against the target tissue which is to be ablated.

Foam 106a is enclosed within a fluid impermeable covering 108a which, as described with respect to previous embodiments, includes a plurality of tiny holes 110a. Holes 110a in the covering 108a may be formed only in the side of the covering at which the foam 106a is thickest. This helps to focus the RF energy onto the target tissue within the heart.

At the ablation section, holes 92a extend from the fluid lumen 82a through the tubing 74a to the foam layer 106a. The holes 92a are located at the side of the ablation section 68a at which the thickened foam region is located to permit the flow of conductive fluid from the fluid lumen 82a to the

foam 106a and then through the holes 110a in the covering.

5 Rather than utilizing coil electrodes of the type described above, the alternative ablation section 68a utilizes conductive wires 94a or flat  
10 conductive ribbons, each of which is covered by an insulated coating. The wires 94a, which extend through the fluid lumen 82a, are preferably 0.005 " in diameter. Exposed electrode regions 96a (Fig. 12D) that are stripped of insulative material are spaced along the portion of the wires 94a that is located within the ablation section 68a.

15 Operation of the embodiment of Figs. 12A - 12E is similar to the operation of the embodiment of Fig. 7 and need not be repeated here.

20 A third embodiment of a linear lesion catheter 114 according to the present invention is shown in Figs. 13A and 13B. Catheter 114 differs primarily from those of the first and second embodiments in that a baffle wire loop protrudes laterally, rather than longitudinally, from the main shaft.

25 This embodiment is generally comprised of a single lumen main shaft 116, an ablation section 118 positioned on the main shaft, and a baffle wire 120 which is slidably disposed within the main shaft 116.

30 Main shaft 116 is preferably constructed of a thermoplastic polymer, polyamid ether, polyurethane or other material having similar properties. A stainless steel braid (not shown) is preferably embedded in the wall of the main shaft by means conventionally known in the art to improve the torque characteristics of the main shaft. A pair of openings 117a, 117b (Fig. 13B) are formed in the side of the main shaft. Each of the openings extends from  
35 the exterior of the main shaft to the interior.

A platinum tip 122 is attached to the distal end of the main shaft 116 by an adhesive. A safety wire 124 may be soldered to the platinum tip 122 and fixed to an interior wall of the main shaft 116 to further insure that the tip 122 does not become detached from the main shaft during use. During use the tip 122 serves as a radiopaque marker which fluoroscopically indicates the position of the distal end of the catheter.

As with the previous embodiments, ablation section 118 includes a plurality of spaced coil electrodes 124, foam support segments 126, lead wires (not shown) and an infusion tube 128.

Infusion tube 128 extends from an infusion port 130 (Fig. 13A) through the main shaft 116 and then passes through an opening 129 in the main shaft 116. Along the ablation section 118, infusion tube 128 extends along the exterior surface of the main shaft 116. As with the infusion tubes 36, 82 (see Figs. 4 and 10) of the first and second embodiments, a plurality of spaced holes (not shown) are preferably formed in the infusion tube to permit infusion of saline into and through the support segments 126.

The lead wires (not shown) extend from a female connector 129 positioned at the distal end of the catheter 114 and then pass through openings in the main shaft 116 (similar to opening 129 through which infusion tube 128 passes) at the ablation section 118.

The coil electrodes 124 are preferably coiled around the infusion tube 128, the electrode leads (not shown) and the main shaft 116 as shown in Fig. 13B. A perforated covering 132 encloses the foam support segments 126 in the manner described with respect to the first and second embodiments.

Baffle wire 120 is preferably formed of metallic stiffening wire, such as stainless steel, enclosed in thin walled shrink tube (not shown, but see Fig. 8C which shows a similar wire 66 and coating 78 configuration). Alternatively, the baffle wire 120 may be formed of a flexible braid tube. Distal end 134 (Fig. 13B) of baffle wire 120 is fixed within the distal end of the main shaft 116, near the platinum tip 122. Baffle wire 120 passes out of the main shaft 116 via opening 117b and re-enters the main shaft via opening 117a to form an arc 135 adjacent the ablation section 118. Proximal end 136 of baffle wire 120 extends freely from a connector port 138 coupled to the proximal end of the main shaft 116 (Fig. 13A).

Operation of the third embodiment of a linear lesion catheter 114 according to the present invention will next be described. To prepare the device for insertion into a patient's vessels, proximal end 136 of baffle wire 120 is pulled in a proximal direction to decrease the size of arc 135 and to thereby draw the arc 135 closer to the main shaft (see Fig. 13A). To facilitate insertion of the catheter 114 into a vessel, it may also be desirable to insert the catheter 114 into a conventional sheath catheter (not shown) so as to compress the ablation section 118 and the arc 135 close to the main shaft and to thereby prevent these structures from snagging on tissue within the vessels and the heart. Once the distal portion of the catheter 112 reaches the desired chamber of the heart, the sheath catheter is withdrawn to expose the ablation section 118 and the arc 135.

Once the ablation section 118 is within the heart chamber and positioned adjacent a region of the endocardium which is to be ablated, proximal end 136

of baffle wire 120 is advanced in a distal direction, as indicated by the arrow in Fig. 13B. Because distal end 134 of the baffle wire 120 is fixed within the main shaft, distal sliding of the baffle wire 120 causes an additional length of the baffle wire 120 to pass out of the main shaft via the hole 117a and thus increases the size of the arc. As the size of the arc increases, the arc pushes against adjacent tissue T1 and thus leverages the ablation section 118 against the portion T2 of the endocardium on which a lesion is to be formed. (See Fig. 13C). Pressing the ablation section 118 against the endocardium in this manner helps the ablation section 118 to conform to the surface of the tissue T2 and thus helps to ensure that sufficient contact is made between the ablation section 118 and the endocardium.

Next, delivery of saline and RF energy to the ablation section 118 is carried out as described with respect to the first and second embodiments to cause the lesion to be formed.

A fourth embodiment of a catheter 140 according to the present invention is shown in Fig. 14. The fourth embodiment is similar to the third in that a baffle wire loop protrudes from the main shaft. It differs from the fourth embodiment in that it includes an ablation section on the baffle wire.

As with the catheter 114 of the third embodiment (Fig. 13A), catheter 140 includes a main shaft 116a, and an ablation section 118a. Main shaft includes a platinum tip 122a similar to the platinum tip 122 of Fig. 13B, and it further includes a pair of holes 119a, 119b. At the proximal end of the main shaft 116 is a connector having an infusion port 130a, a second port 138a, and a female connector 129a.

A baffle wire 120a extends through the main shaft 116a and includes a distal end 134a fixed to the distal end of the main shaft 116a. A free proximal end 136a extends from connector port 138a in the main shaft. A section of the baffle wire 120a extends through holes 119a, 119b in the main shaft 116a to form an arc 135a.

As with the above-described embodiments, ablation section 118a preferably includes a perforated covering 132a, foam support segments 126a, coil electrodes 124a, lead wires (not shown) and an infusion tube (not shown). These elements are arranged on the arc 135a formed by baffle wire 120a in a manner which is preferably similar to the manner in which the covering 44, foam 42, electrodes 40, leads 39, baffle wire 20, and infusion tube 36 are arranged in the first embodiment. Reference is therefore made to Figs. 4 and 5 and the description thereof.

Operation of the fourth embodiment of a linear lesion catheter 140 according to the present invention will next be described. To prepare the device for insertion into a patient's vessels, free end 136a of baffle wire 120a is pulled in a proximal direction to draw the arc 135a closer to the main shaft (see Fig. 14A). The catheter 140 may be inserted into a conventional sheath catheter (not shown) so as to compress the ablation section 118a and the arc 135a close to the main shaft 116a to prevent these structures from snagging on tissue within the vessels and the heart. The sheath catheter is withdrawn to expose the ablation section 118 after the distal portion of the catheter 112a has been fed through the patient's vessels and positioned in the desired chamber of the heart.

Once the ablation section 118a is within the heart chamber, free end 136a of baffle wire 120a is advanced in a distal direction, causing a portion of the baffle wire 120a to pass out of the main shaft via the hole 119a thereby increasing the size of the arc 135a. As the size of the arc increases, the arc and the main shaft push against opposing tissue surfaces T1, T2 and thus leverage the ablation section 118a against the portion T2 of the endocardium on which a lesion is to be formed. (See Fig. 14C). Pressing the ablation section 118a against the endocardium in this manner helps the ablation section 118a to conform to the surface of the endocardium and thus helps to ensure that sufficient contact is made between the ablation section 118 and the endocardium to create a continuous transmural lesion.

Once the ablation section is properly positioned and baffled against the appropriate section of the endocardium, saline and RF energy are delivered to the ablation section 118 as described with respect to the first and second embodiments. The procedure is repeated to create multiple lesions on the endocardium.

It should be understood that the various features of the preferred embodiments need not be used in combination one other. For example, referring to Fig. 15A, a catheter 200 according to the present invention may be provided without a baffle wire as found in the previously described embodiments. Catheter 200 includes a main shaft 202 (preferably having a diameter of 7 French) and an ablation section 204 formed over the main shaft 202.

At the ablation section 204, a plurality of electrodes 206 are coiled around the main shaft 202, and (also at the ablation section 204) a plurality of

spaced holes 208 are formed in the main shaft. A foam support structure 210 (which may be segmented as in prior embodiments) is formed around the main shaft and electrodes 206, and the support structure 210 is enclosed by a perforated covering 212. A core wire 214 extends through the central lumen of the main shaft 202. Wire 214 may alternatively be a pull wire of a type which may be used to steer the catheter 200 through a patient's vessels and heart.

As shown in Fig. 15B, foam segments 210a may each be provided with separate coverings 212a, each of which is provided with a plurality of holes 211 along one side. It is desirable to provide four such 20 mm wide segments 210a, each spaced from the other segments 210a by approximately 1 mm. Preferable, multiple lumen tubing having the configuration shown in Figs. 12B and 12C is utilized, with each of the fluid lumen (see lumen 82a in Figs. 12B and 12C) directing fluid from one of the fluid portions 88a - 88d to one of the foam segments 210a.

During use the catheter 200 is inserted via vessels into a chamber of the heart, and positioned against the endocardial surface. Saline S is introduced into the central lumen of main shaft 202 (which in this embodiment serves as the infusion tube) and passes through the holes 208 into the foam structure 210. RF energy is delivered to the electrodes 206 via lead wires (not shown) as described with respect to previous embodiments.

The outward pressure of the saline S within covering 212 causes the covering 212 to balloon out slightly and thereby improves contact between the ablation section 204 and the endocardium. Saline passes from the foam out of the ablation section via the perforations (not shown) in the covering 212 and



in doing so creates an improved path of conductivity between the electrodes 206 and the endocardium.

As mentioned above, the foam support structure of the Fig. 15A embodiment and the previous  
5       embodiments may be replaced by other support structures which can press the covering of the ablation section against the endocardial wall during use. For example, small inflatable balloons 215  
10       (Fig. 16) may be positioned inside the covering 212 and provided with inflation tubes 216 which provide flow paths for the introduction of an inflation medium (such as air or fluid) into the balloons 215 during use. Alternatively, the foam and covering may be eliminated from the apparatus as shown in Fig. 17,  
15       in which case the conductive fluid or saline flows through openings 208 in the main shaft and is utilized primarily to cool the ablation electrodes 206, although it may also create a conductive path between the electrodes and target tissue. The  
20       electrodes 206 may be formed into coils, braids, or other configurations.

A preferred embodiment and several alternative embodiments of a linear lesion catheter have been described herein. It should be appreciated that  
25       these embodiments have been given by way as example and are not intended to limit the scope of the appended claims.

CLAIMS

1. An apparatus for creating linear lesions in body tissue, the apparatus comprising:

5 an elongate support member proportioned for insertion and manipulation through human vessels, the support member having an elongate ablation section;

at least one electrode carried by the ablation section of the support member;

10 a fluid permeable deformable member at least partially covering the electrodes;

means for delivering current to the electrodes; and

15 means for delivering conductive fluid through the deformable member to the ablation section to cause said fluid to create a conductive path between the electrodes and the tissue when the electrodes are positioned adjacent body tissue.

20 2. The apparatus of claim 1 wherein the deformable member includes a layer of foam material formed over the electrodes.

25 3. The apparatus of claim 1 wherein the deformable member is segmented.

30 4. The apparatus of claim 1, further comprising a covering on the deformable member, the covering formed of a material substantially impermeable to fluid, the covering including at least one opening sized to allow passage of fluid out of the covering.

35 5. The apparatus of claim 4 wherein the covering includes a plurality of spaced openings

positioned longitudinally along one side of the ablation section.

5           6.    The apparatus of claim 1 wherein the deformable layer is provided in segments and wherein the apparatus further comprises a plurality of coverings, each covering one of the segments.

10           7.    An apparatus for creating lesions in body tissue, the apparatus comprising:  
            an elongate wire having an ablation section;  
            a plurality of spaced electrodes carried by the ablation section of the wire;  
            a covering at least partially overlaying the  
15           electrodes, the covering formed of a material substantially impermeable to fluid, the covering including at least one opening sized to allow passage of fluid out of the covering;  
            means for delivering current to the electrodes;  
20           and  
            ~~means for delivering conductive fluid to the~~  
            ablation section to cause said fluid to create a  
            conductive path between the electrodes and the tissue  
            when the electrodes are positioned adjacent body  
25           tissue.

            8.    The apparatus of claim 7 further comprising means for supporting the covering away from the electrodes.

30           9.    The apparatus of claim 8 wherein the supporting means includes a deformable member positioned between the electrodes and the covering, the deformable member being fluid permeable.

10. The apparatus of claim 9 wherein the deformable member includes a layer of foam formed over the electrodes.

5           11. The apparatus of claim 8 wherein the supporting means includes an inflatable balloon positioned beneath the covering and means for delivering an inflation medium to the inflatable balloon.

10           12. A method for ablating body tissue, comprising the steps of:

          (a) providing an elongate member, electrodes carried by the member, a deformable layer of fluid permeable material formed over the electrodes, and  
15           means for delivering conductive fluid to the electrodes;

          (b) manipulating the member through a vessel and into the chamber of a heart, and positioning the  
20           layer adjacent to a wall within the heart which is to be ablated;

          (c) supplying current to the electrodes;

          (d) supplying conductive fluid to the electrodes; and

25           (e) permitting the conductive fluid to form a conductive path between the electrodes and the tissue which is to be ablated.

30           13. The method of claim 12 wherein step (a) further includes the step of providing a covering the deformable layer, the covering formed of a material substantially impermeable to fluid, the covering including at least one opening sized to allow passage  
35           of fluid out of the covering, and wherein step (b) further includes the step of positioning the

deformable layer, with the covering overlaying it, against the body tissue which is to be ablated.

5 14. An apparatus for ablating body tissue, comprising:

an elongate tubular member having an opening;  
a baffle member having a distal portion slidably disposed within the tubular member, the baffle member slidable between a first position in which the distal portion extends from the opening and is folded over  
10 itself, and a second position in which the distal portion of the baffle member is contained within the elongate tubular member; and  
an ablation element carried by the baffle  
15 member.

15 15. The apparatus of claim 14 wherein the baffle member includes a fixed distal end attached to the tubular member and a free proximal end slidable  
20 relative to the tubular member to move the baffle member between the first and second positions.

25 16. The apparatus of claim 14 wherein the baffle member has a substantially flat cross-section.

17. The apparatus of claim 15 wherein:  
the apparatus further comprises a second tube, wherein a portion of the baffle member is slidably received within the second tube;  
30 the ablation element is carried by the second tube; and  
when the baffle member is in the first position, the second tube is slidable over the loop to reposition the ablation element with respect to the  
35 loop.

18. The apparatus of claim 14 wherein the baffle member includes a pair of free ends, each slidable to move the baffle member between the first and second positions.

5

19. A method of forming a linear lesion, comprising the steps of:

10 (a) providing an elongate tubular member having a distal portion, an opening at the distal portion, a loop positioned within the distal portion and moveable through the opening to a position outside the distal portion, and an ablation element carried by the loop;

15 (b) with the loop inside the tubular member, inserting the distal portion of the tubular member through an incision and into a patient, and positioning the opening adjacent to target tissue to be ablated;

20 (c) extending the loop from the distal portion;  
(d) positioning the ablation element against the target tissue;

25 (e) positioning a portion of the loop which is spaced from the ablation element against a tissue surface opposing the target tissue to leverage the electrode against the target tissue; and

(f) ablating the tissue using the ablation element.

30 20. The method of claim 19 wherein step (e) includes the step of increasing or decreasing the size of the loop.

21. The method of claim 19 wherein:

35 step (a) includes providing a tubular member slidably disposed on the loop and providing the ablation element on the tubular member; and

step (d) includes the step of sliding the tubular member along the loop to adjust the position of the ablation element with respect to the loop.

5           22. The method of claim 21 further including the step of, after step (f), sliding the tubular member along the loop to reposition the ablation element adjacent to second target tissue, and  
10           ablating the second target tissue using the ablation element.

          23. The method of claim 19 wherein:  
          in step (a) the step of providing a loop includes providing a baffle member having a fixed end  
15           attached to the tubular member, an intermediate portion folded over itself to form the loop, and a free end movable to effect sliding of the baffle wire to move the loop into and out of the tubular member and to change the size of the loop;

20           step (c) includes the step of advancing the free end distally to extend the loop from the tubular member;

          steps (d) and (e) include the step of moving the free end distally or proximally as needed to increase  
25           or decrease the size of the loop.

          24. The method of claim 23 wherein:  
          step (a) further comprises the step of providing a tubular member slidably disposed on the baffle wire  
30           and providing the ablation element on the tubular member; and

          step (d) includes the step of sliding the tubular member along the loop to adjust the position of the ablation element with respect to the loop.  
35

25. The method of claim 25 further including the step of, after step (f), sliding the tubular member along the loop to reposition the ablation element adjacent to second target tissue, and  
5 ablating the second target tissue using the ablation element.

26. The method of claim 20 wherein:  
in step (a) the step of providing a loop  
10 includes providing a baffle member having a pair of free ends and an intermediate portion between the ends and folded over itself to form the loop, the free ends movable to effect sliding of the baffle wire to move the loop into and out of the tubular member and to change the size of the loop;  
15 step (c) includes the step of advancing at least one of the free ends distally to extend the loop from the tubular member; and  
steps (d) and (e) include the step of moving at  
20 least one of the free ends distally or proximally as needed to increase or decrease the size of the loop.

27. An assembly carried on the distal end of a catheter for generating a linear lesion in a target  
25 tissue comprising:  
a central, elongated support member;  
a plurality of longitudinally spaced apart electrodes, said electrodes being connectable to a source of RF energy;  
30 an elongated, deformable member surrounding said electrodes and a portion of said support member; and  
a source of electrolytic fluid coupled to said deformable member, said fluid functioning  
35 to partially pressurize said deformable member and wherein said fluid perfuses out of said



5           deformable member towards the target tissue,  
          said fluid enhancing the coupling of the RF  
          energy from said electrodes to said tissue  
          whereby linear lesions can be effectively  
          created in said tissue.

10           28. An assembly as recited in claim 27 wherein  
          said deformable member is formed in longitudinal  
          segments corresponding to, and aligned with, the  
          electrodes on said support member.

          28. An assembly as recited in claim 27 wherein  
          said support member is a wire.

15           29. An assembly as recited in claim 27 wherein  
          said deformable member is formed from foam surrounded  
          by an outer membrane having apertures formed therein.

20           30. An assembly as recited in claim 27 wherein  
          said deformable member includes an inflatable  
          balloon,—an outer membrane enclosing the balloon and  
          having apertures formed therein, and means for  
          delivering an inflation medium to the inflatable  
          balloon.

25           31. An assembly as recited in claim 27 further  
          including a means for biasing said deformable member  
          into contact with the target tissue.

30           32. An assembly as recited in claim 31 further  
          comprising an elongate tubular member having an  
          opening, wherein the central support member is  
          slidably disposed within the elongate tubular member  
          and wherein the central support member is slidable  
35           between a first position in which the distal portion  
          extends from the opening and is folded over itself,

and a second position in which the distal portion of the baffle member is contained within the elongate tubular member, wherein the biasing means includes the central support member, and wherein the electrodes and the deformable member are carried by the central support member.

33. An assembly carried on the distal end of a catheter for generating a linear lesion in a target tissue comprising:

a central, elongated support member;

a plurality of longitudinally spaced apart electrodes carried by the support member, said electrodes being connectable to a source of RF energy; and

means carried by the support member for directing electrolytic fluid onto said electrodes.

## AMENDED CLAIMS

[received by the International Bureau on 15 July 1997(15.07.97);  
original claim 32 amended; new claims 34-38 added;  
remaining claims unchanged (3 pages)]  
deformable member towards the target tissue,  
said fluid enhancing the coupling of the RF  
energy from said electrodes to said tissue  
whereby linear lesions can be effectively  
created in said tissue.

5

28. An assembly as recited in claim 27 wherein  
said deformable member is formed in longitudinal  
segments corresponding to, and aligned with, the  
electrodes on said support member.

10

28. An assembly as recited in claim 27 wherein  
said support member is a wire.

15

29. An assembly as recited in claim 27 wherein  
said deformable member is formed from foam surrounded  
by an outer membrane having apertures formed therein.

20

30. An assembly as recited in claim 27 wherein  
said deformable member includes an inflatable  
balloon, an outer membrane enclosing the balloon and  
having apertures formed therein, and means for  
delivering an inflation medium to the inflatable  
balloon.

25

31. An assembly as recited in claim 27 further  
including a means for biasing said deformable member  
into contact with the target tissue.

30

32. An assembly as recited in claim 31 further  
comprising an elongate tubular member having an  
opening, wherein the central support member is  
slidably disposed within the elongate tubular member

and wherein the central support member is slidable between a first position in which the distal portion extends from the opening and is folded over itself, and a second position in which the distal portion of the central support member is contained within the elongate tubular member, wherein the biasing means includes the central support member, and wherein the electrodes and the deformable member are carried by the central support member.

33. An assembly carried on the distal end of a catheter for generating a linear lesion in a target tissue comprising:

a central, elongated support member;

a plurality of longitudinally spaced apart electrodes carried by the support member, said electrodes being connectable to a source of RF energy; and

means carried by the support member for directing electrolytic fluid onto said electrodes.

34. An apparatus for forming linear lesions in body tissue, comprising:

a first tubular member;

a loop member slidably disposed within the first tubular member, at least one of the first tubular member and loop member slidable to alter the position of the first tubular member relative to the loop member;

a plurality of longitudinally spaced apart electrodes carried by the first tubular member,

said electrodes being connectable to a source of RF energy;

a fluid lumen carried by the first tubular member for directing electrolytic fluid onto  
5 said electrodes; and

an elongated deformable member surrounding the electrodes and a portion of the first tubular member.

10 35. The apparatus of claim 34, further comprising:

a covering on the deformable member, the covering formed of a material substantially impermeable to fluid, the covering including at  
15 least one opening sized to allow passage of fluid out of the covering.

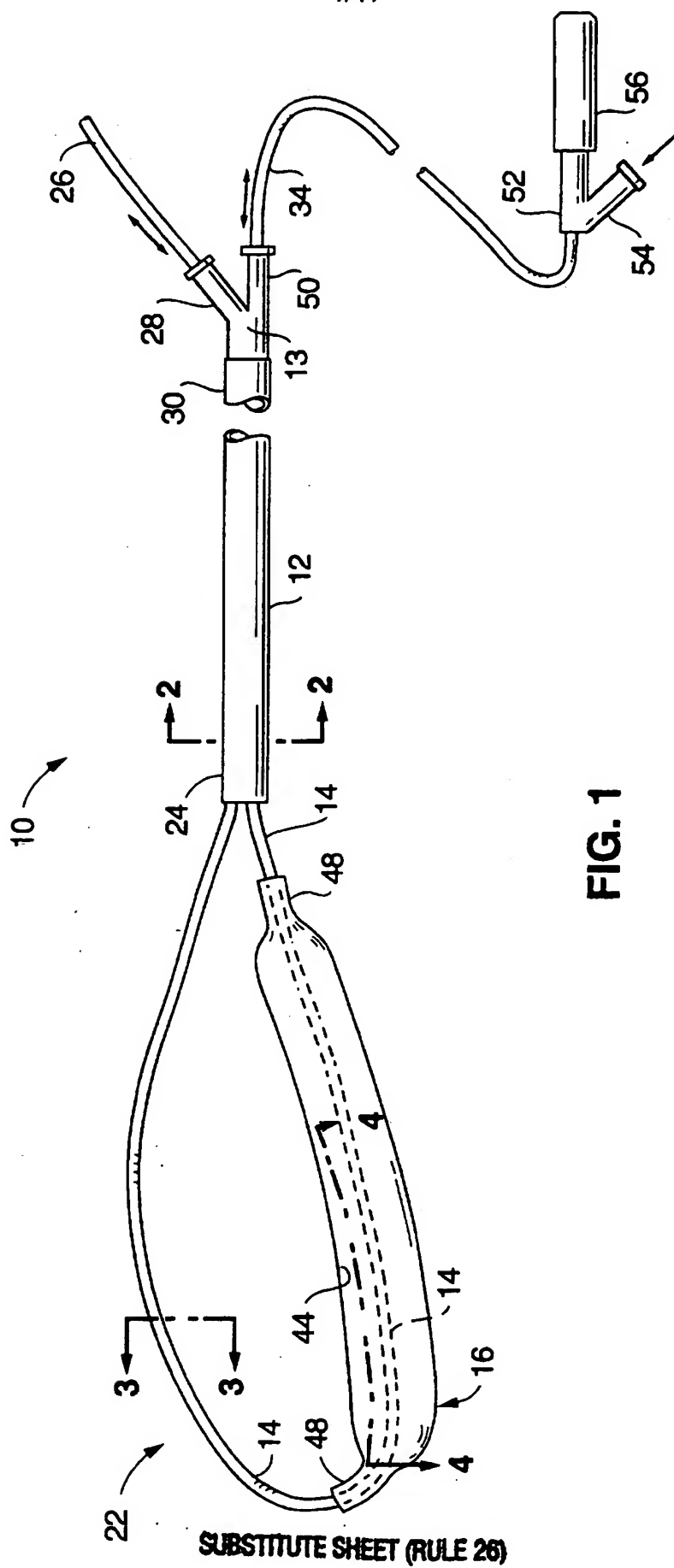
36. The apparatus of claim 34 further comprising:

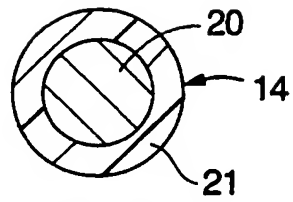
20 a second tubular member, wherein at least a portion of the first tubular member and the loop member are slidably disposed within the second tubular member.

25 37. The apparatus of claim 34 wherein the electrodes are located on the exterior of the first tubular member.

30 38. The apparatus of claim 34 wherein the electrodes are positioned in the fluid lumen.

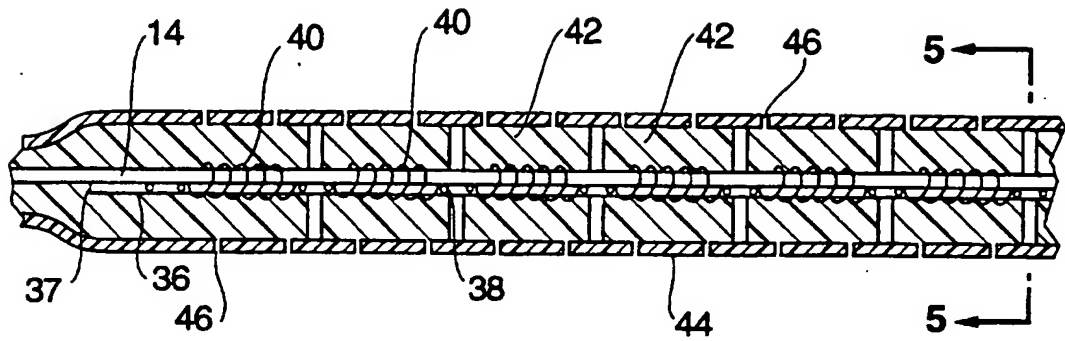
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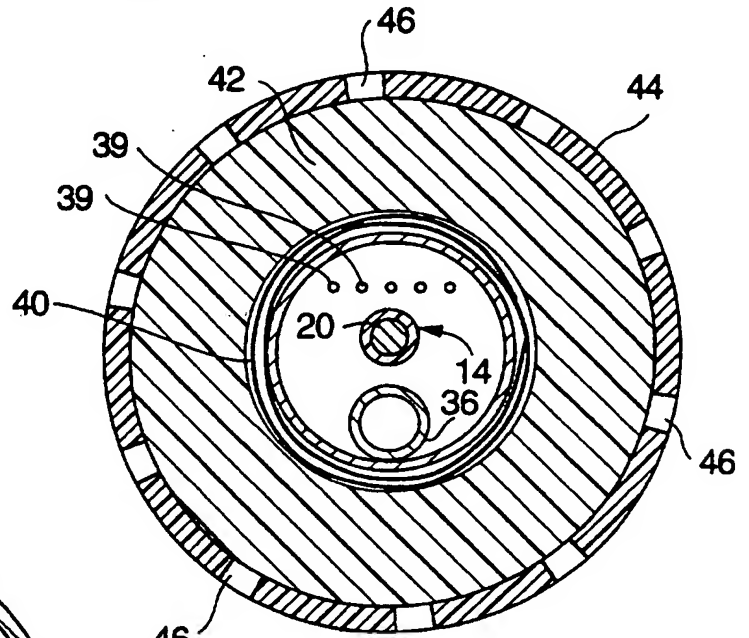


**FIG. 3**

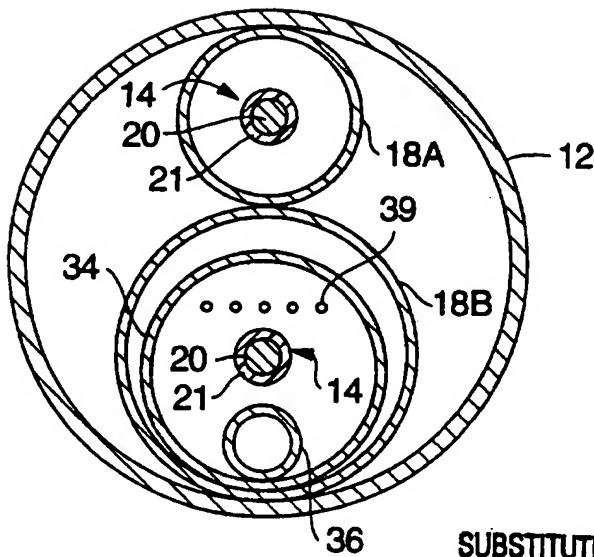
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**FIG. 4**

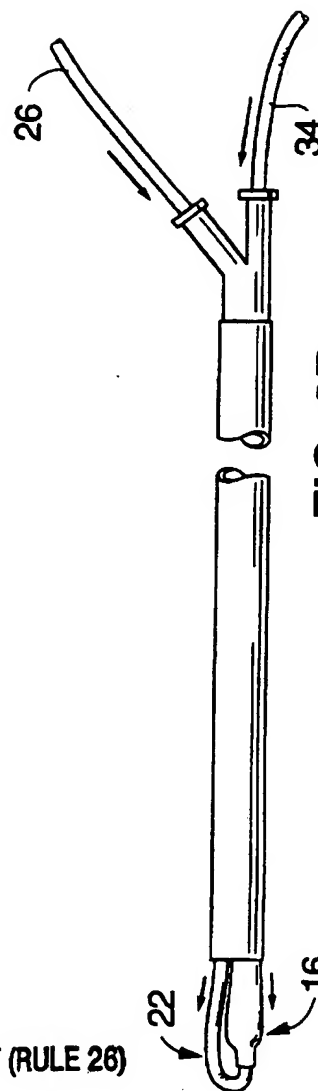
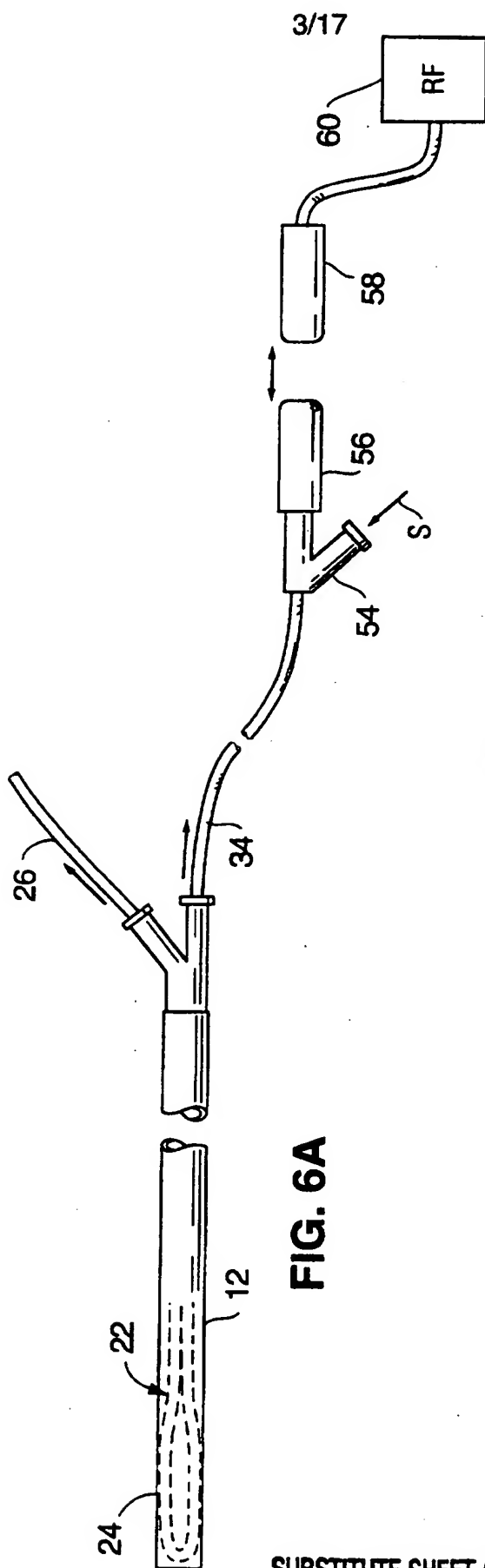


**FIG. 5**



**FIG. 2**

SUBSTITUTE SHEET (RULE 26)





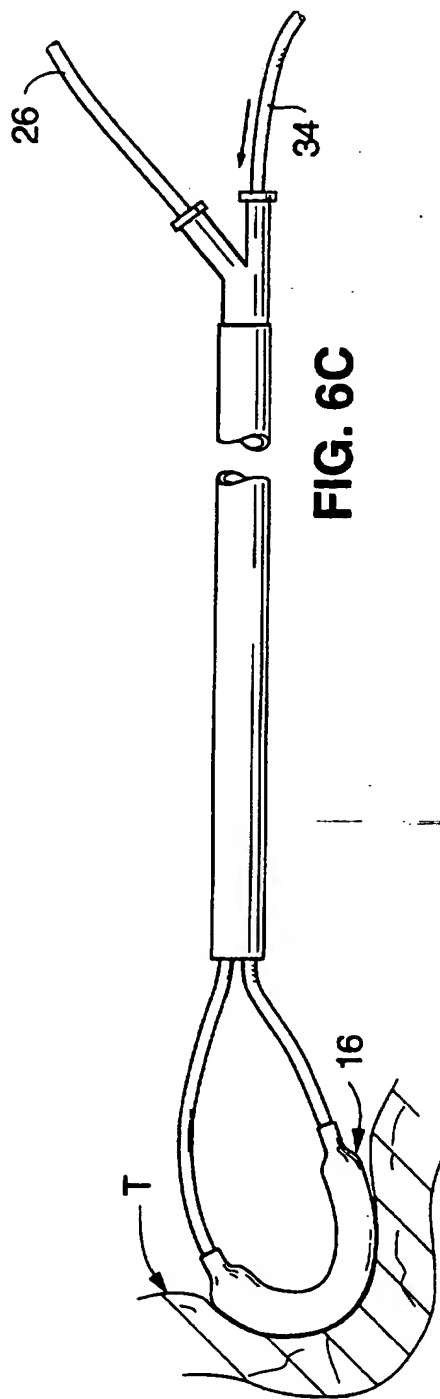


FIG. 6C

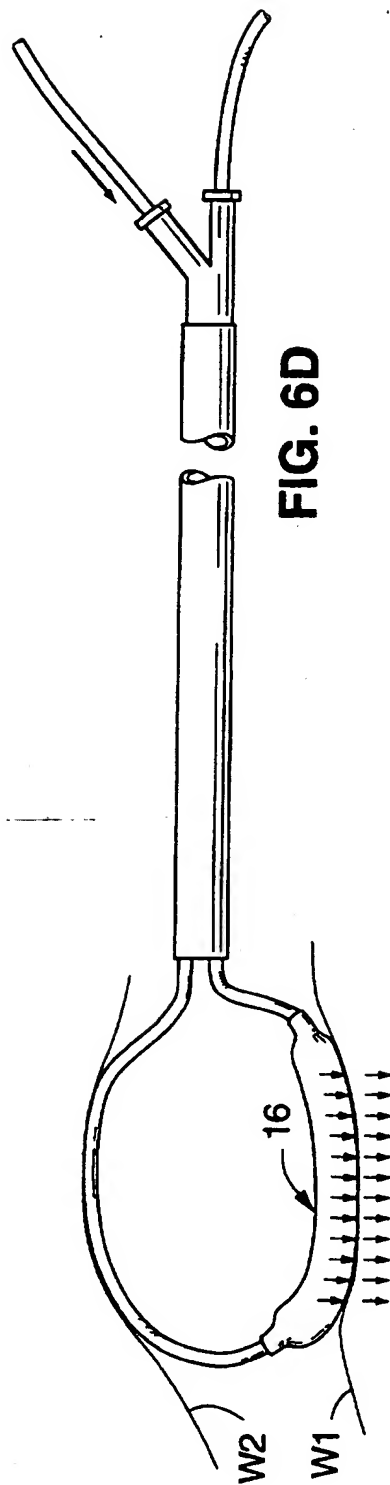
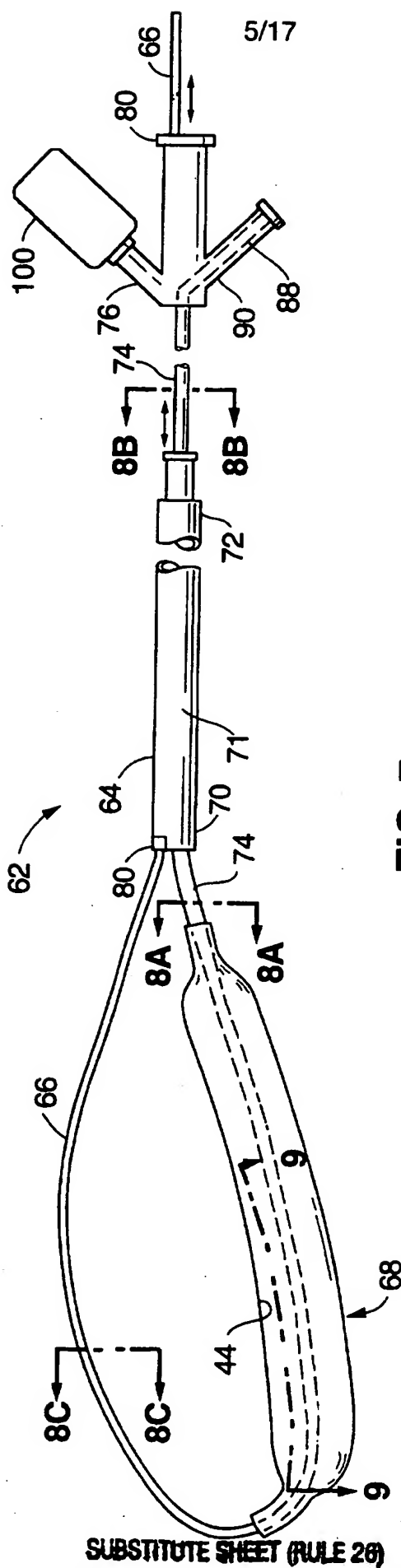
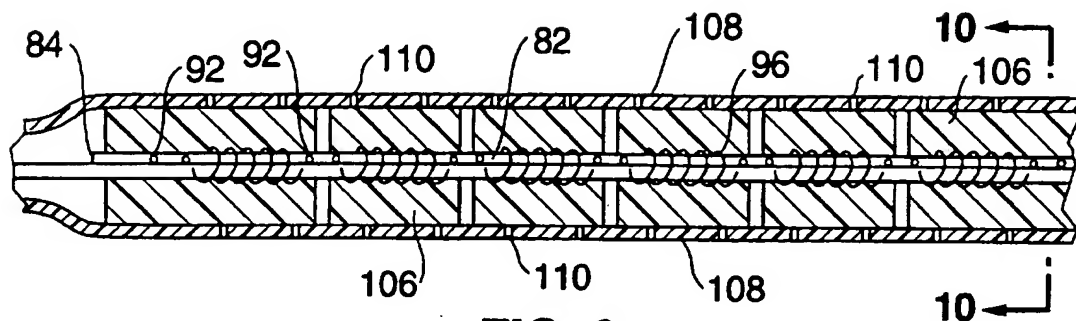


FIG. 6D

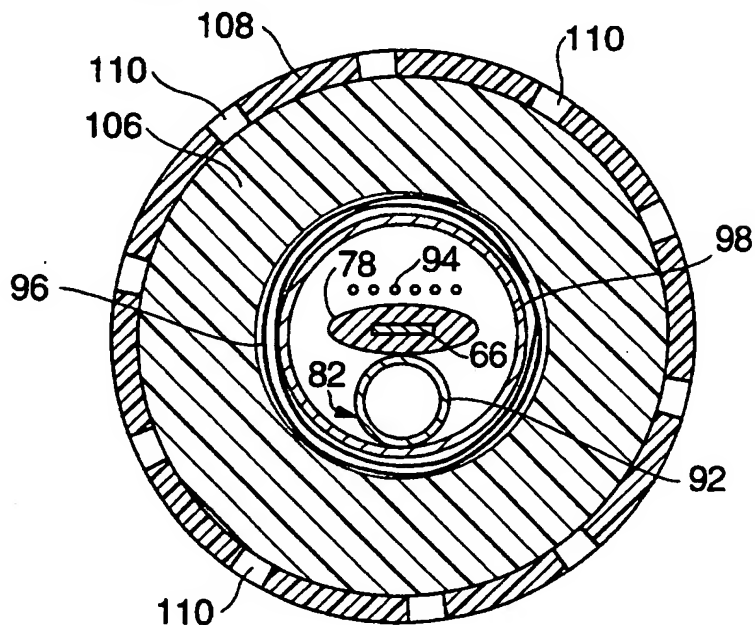




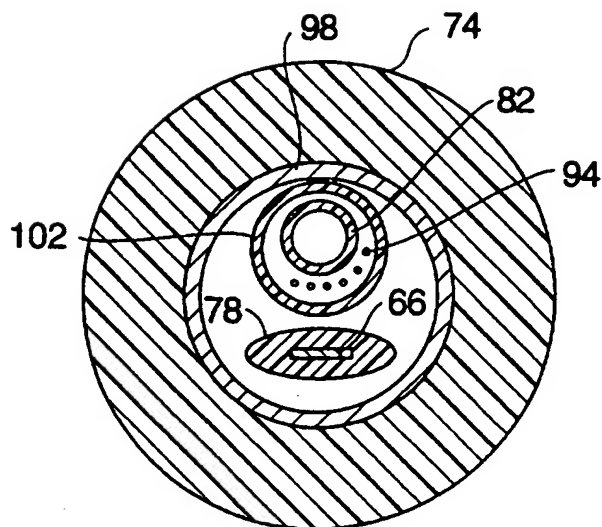
**FIG. 8C**



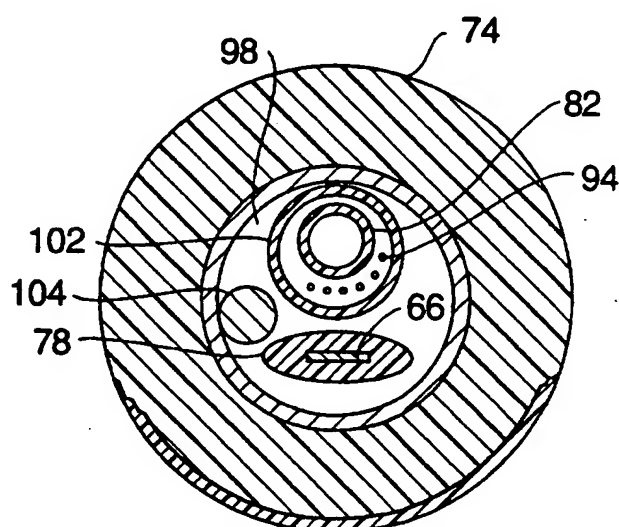
**FIG. 9**



**FIG. 10**



**FIG. 8A**



**FIG. 8B**

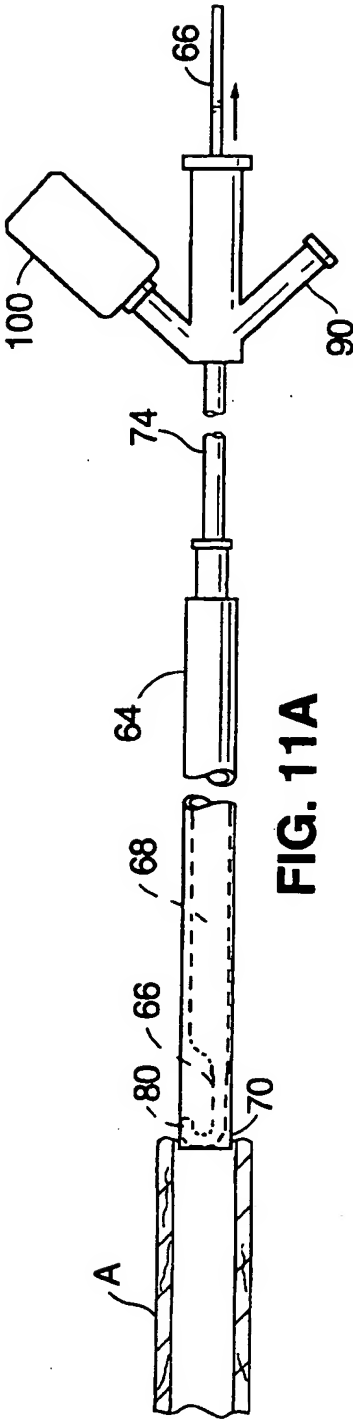


FIG. 11A

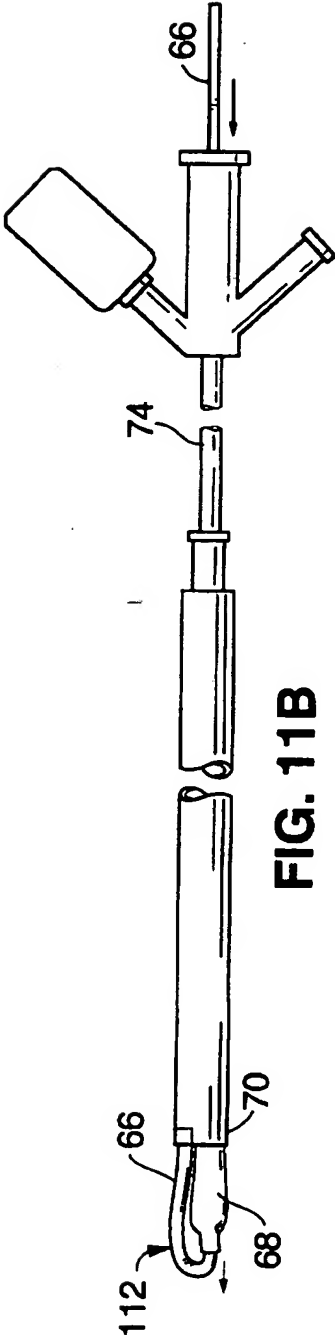
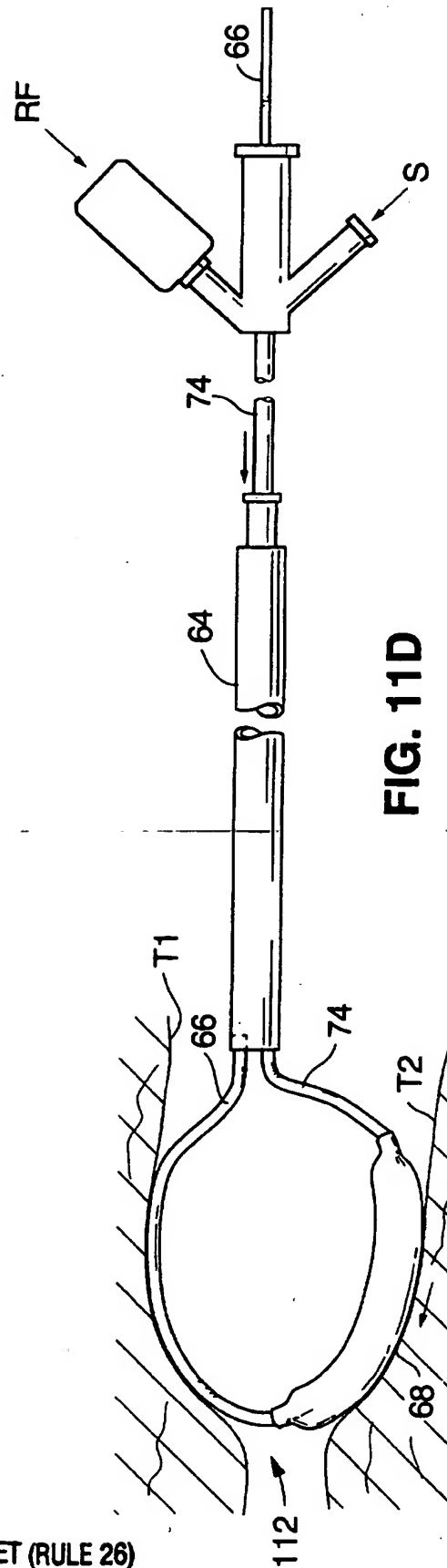
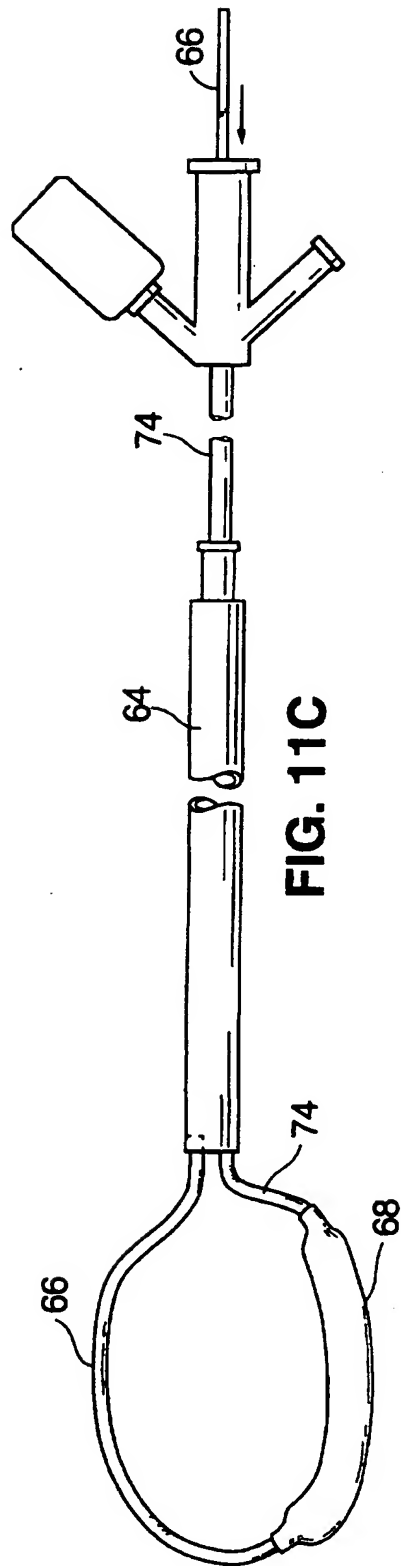


FIG. 11B

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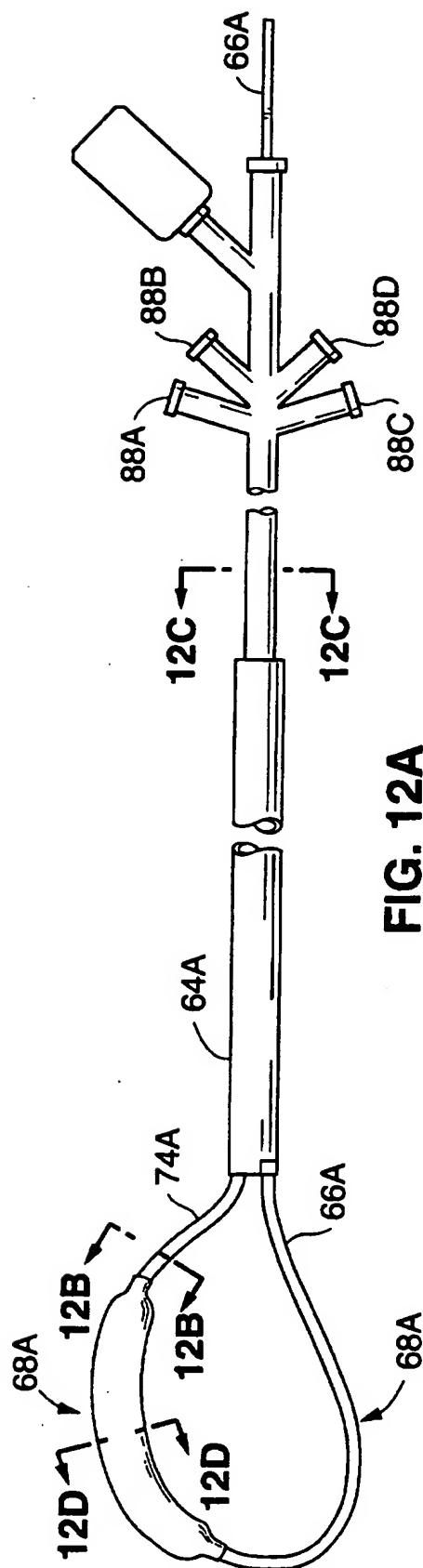
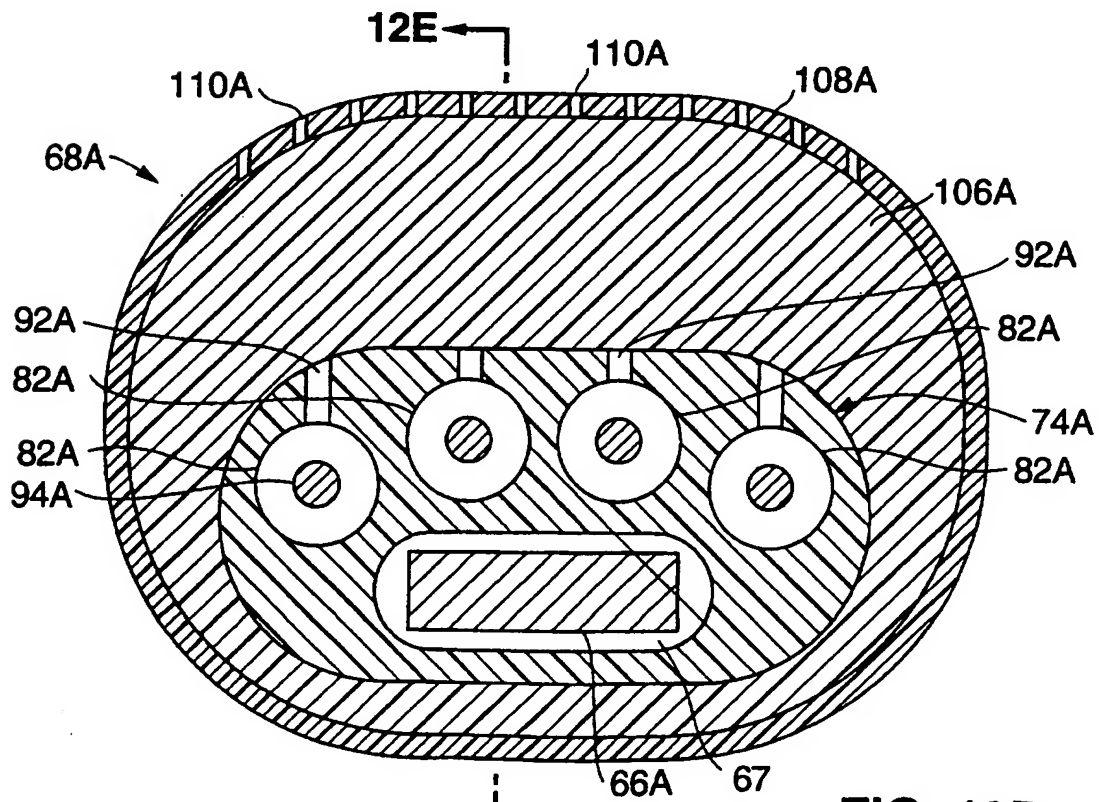
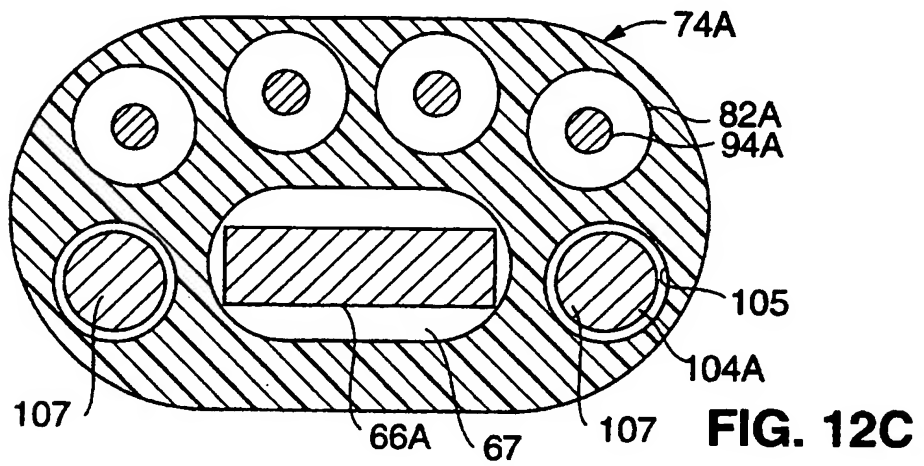
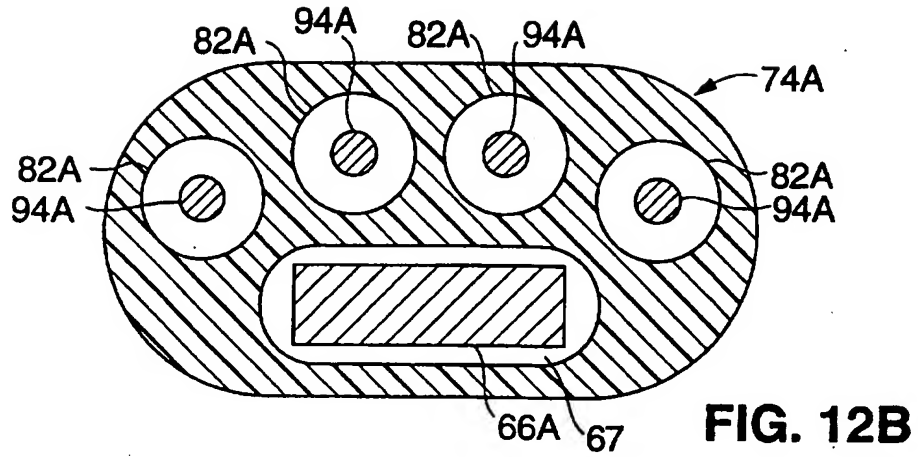


FIG. 12A



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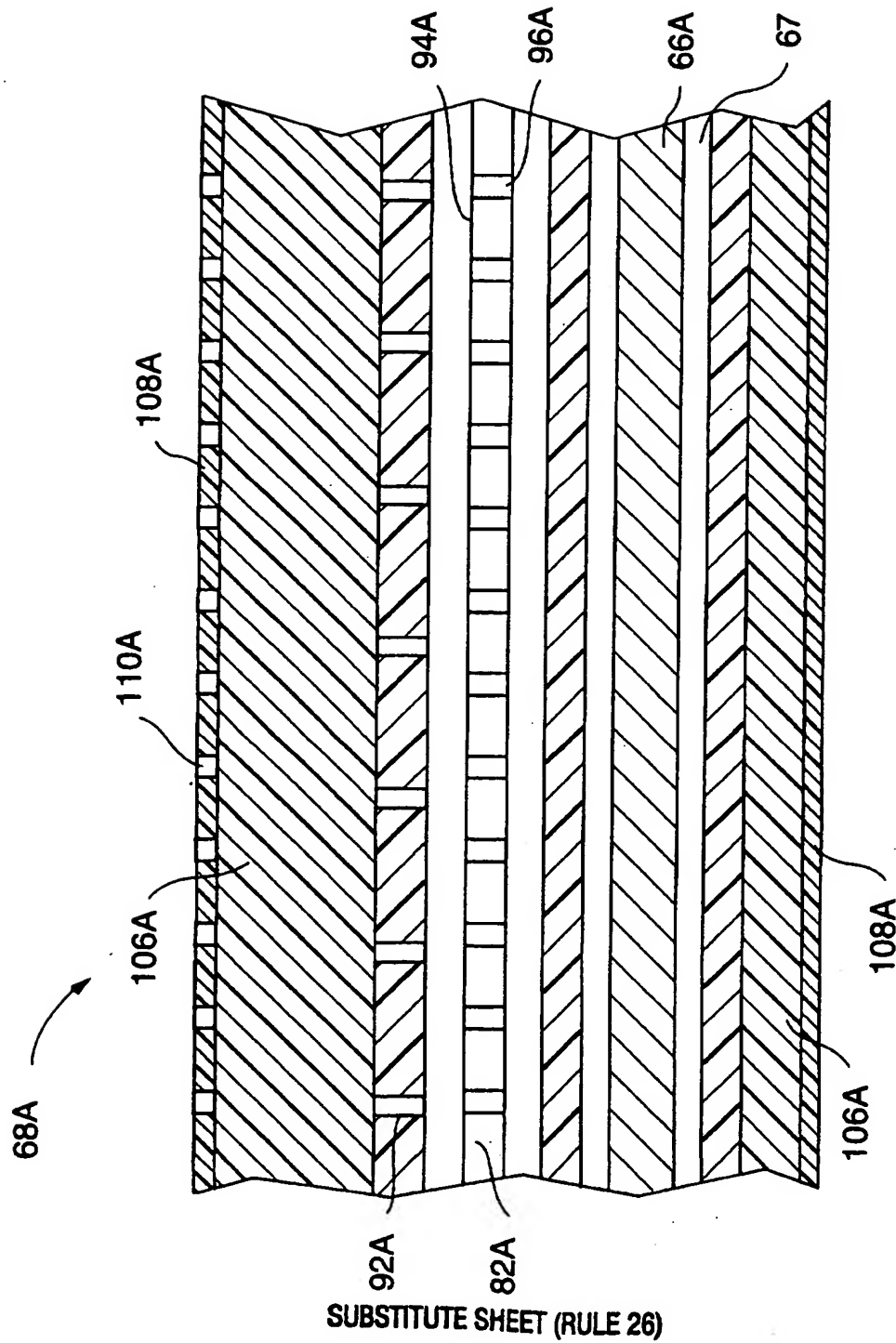
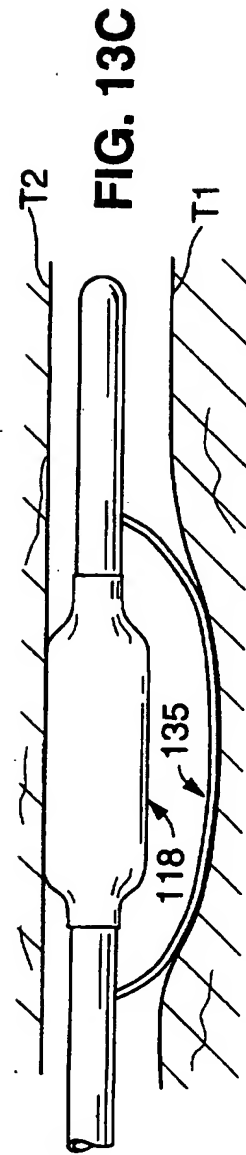
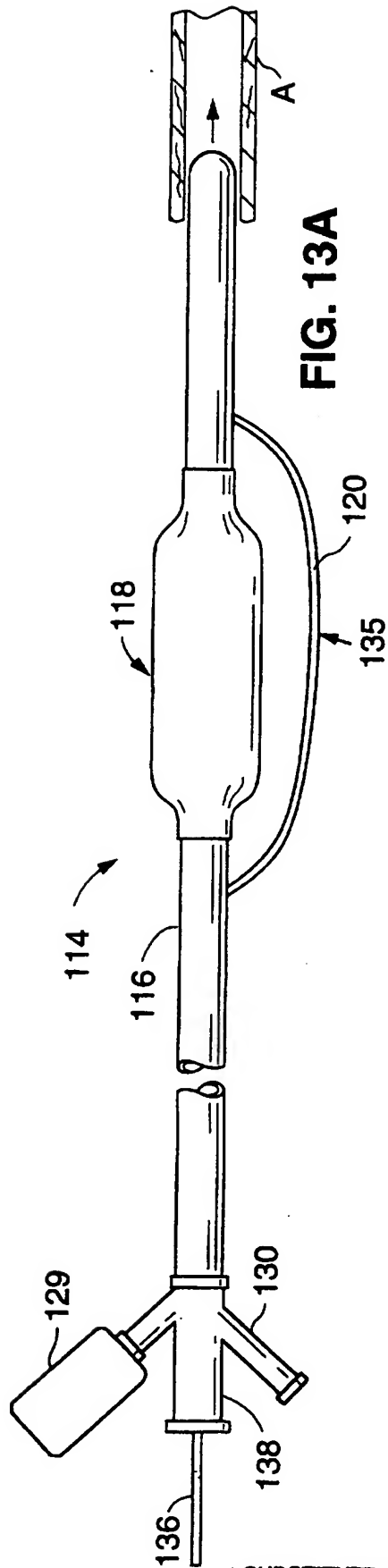
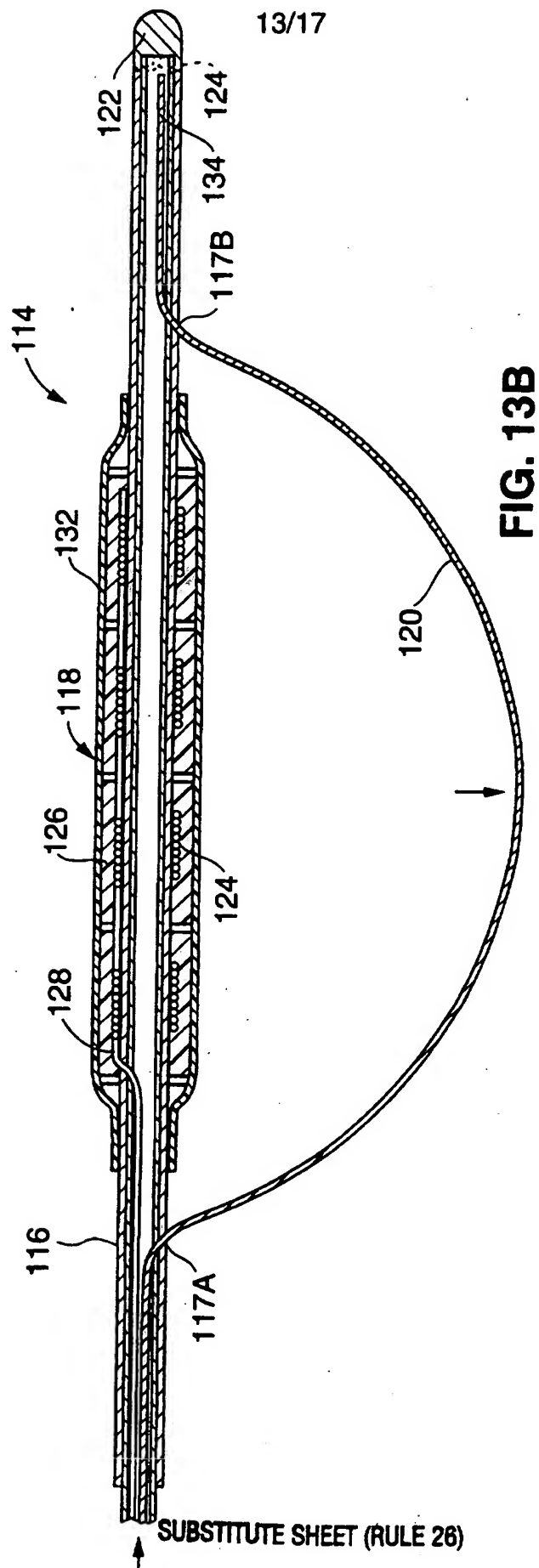


FIG. 12E



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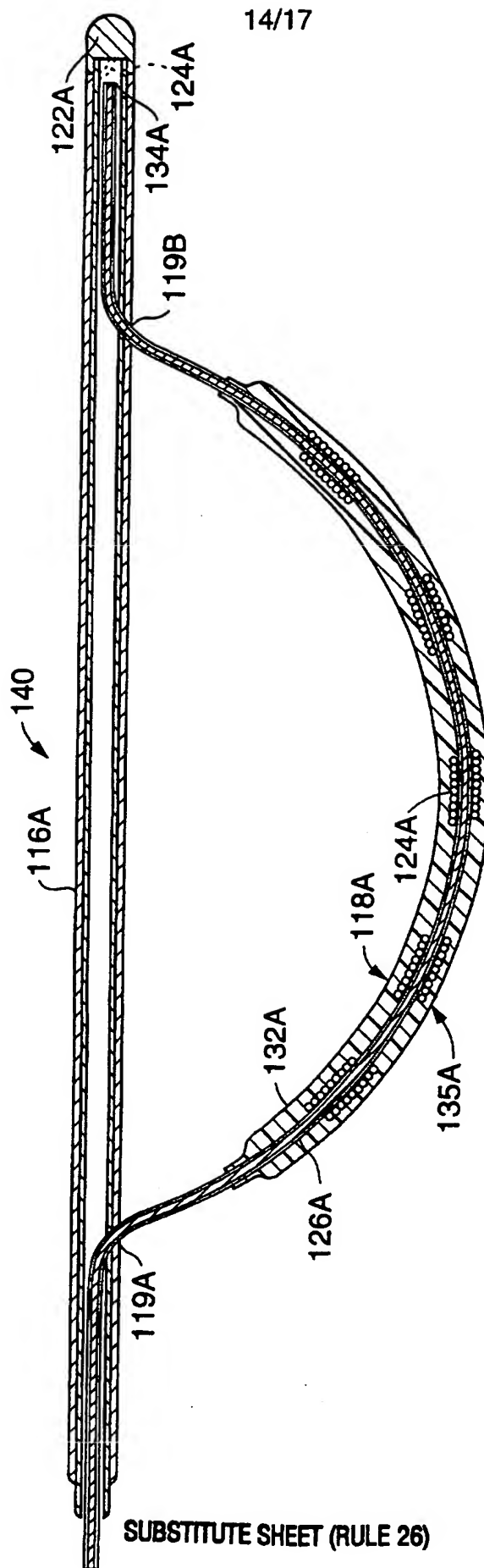


FIG. 14B

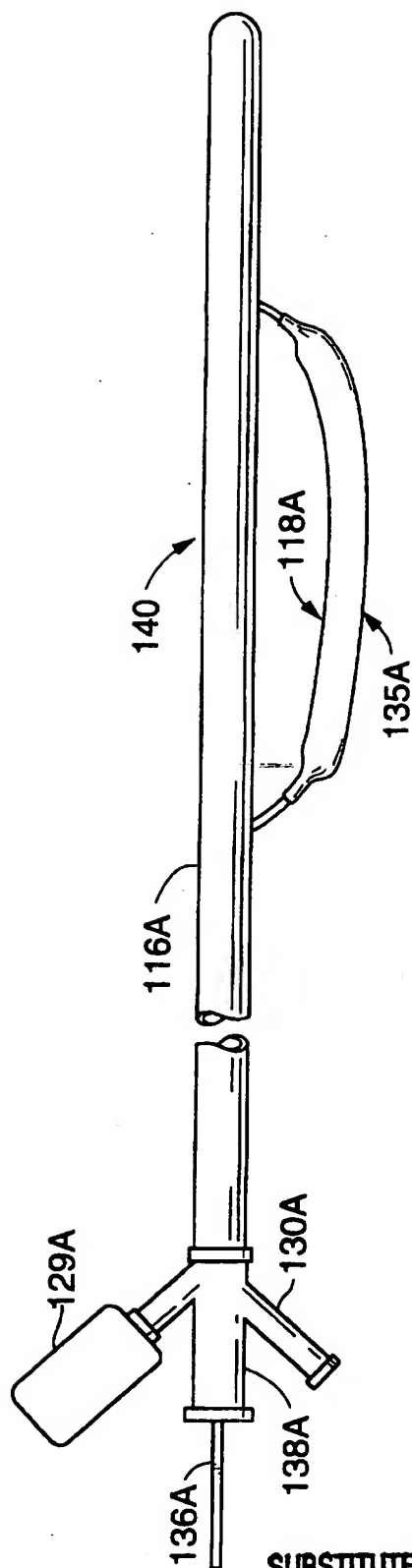


FIG. 14A

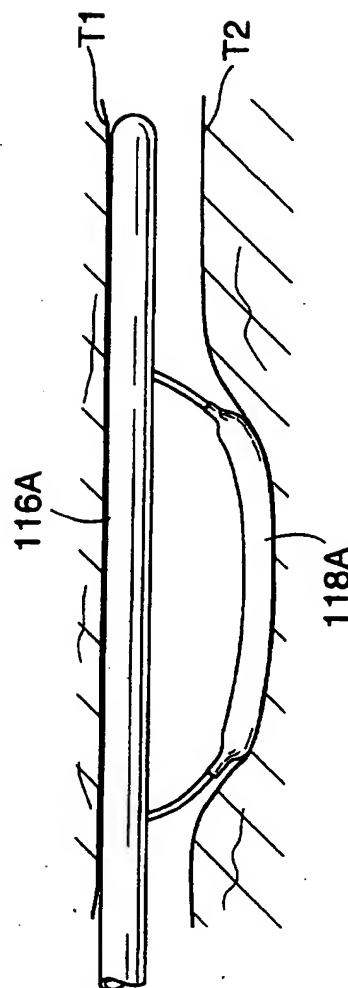


FIG. 14C

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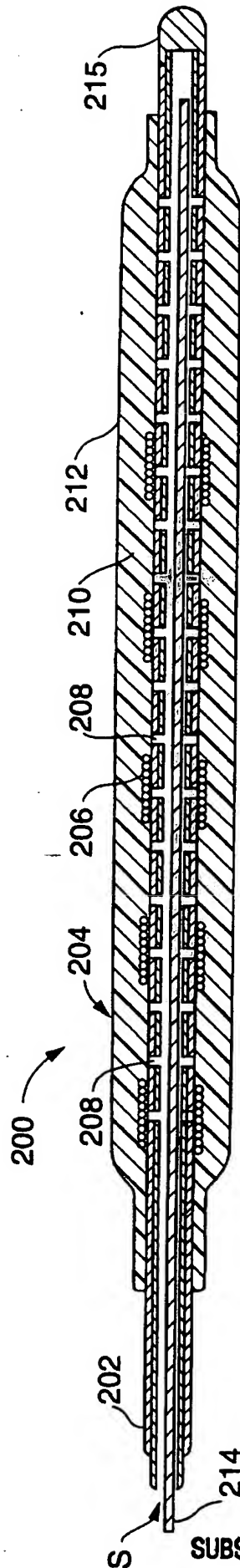


FIG. 15A

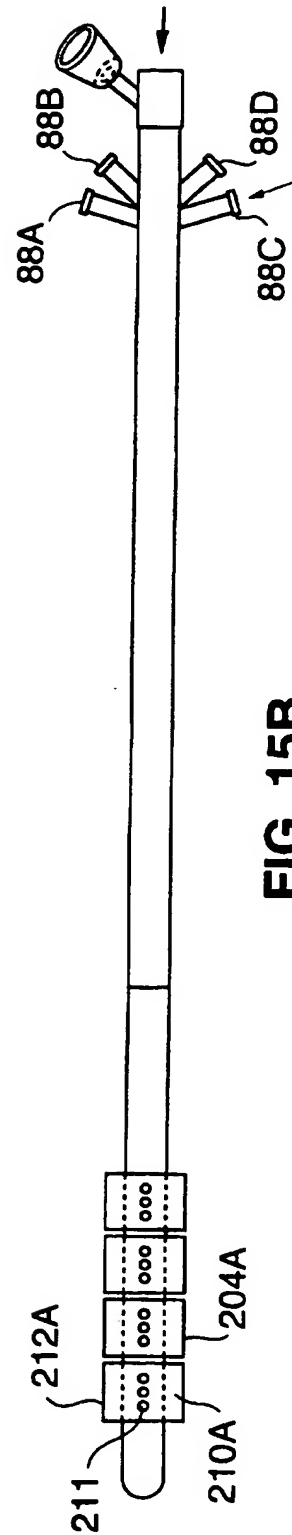


FIG. 15B

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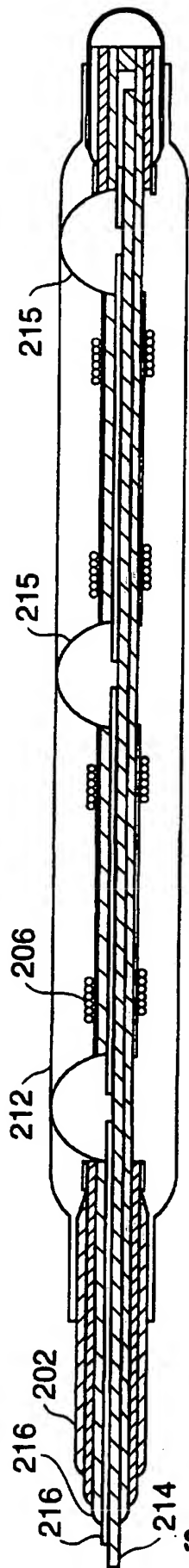


FIG. 16

SUBSTITUTE SHEET (RULE 26)

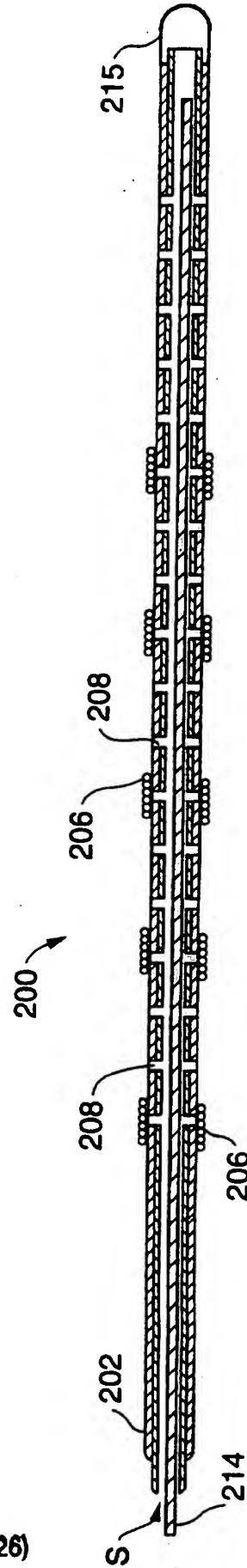


FIG. 17

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 96/17536

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61B17/00 A61B17/39 A61B1/05

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 34346 A (SCIMED) 21 December 1995	1,2,27, 33
Y	see page 4, last paragraph - page 5; figures 1,3	3-5, 7-11,28, 29,31
A		14,30
Y	US 4 850 351 A (HERMAN) 25 July 1989	3,28
A	see abstract; figures 3,4	6
A	US 5 454 370 A (AVITALL) 3 October 1995	3,28
	see abstract; figures 3-6	
Y	WO 90 07909 A (APPLIED UROLOGY) 26 July 1990	31
A	see figures 1,2	30
	--- -/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

- \*"A" document defining the general state of the art which is not considered to be of particular relevance
- \*"E" earlier document but published on or after the international filing date
- \*"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*"O" document referring to an oral disclosure, use, exhibition or other means
- \*"P" document published prior to the international filing date but later than the priority date claimed

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- \*"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- \*"&" document member of the same patent family

Date of the actual completion of the international search

25 April 1997

Date of mailing of the international search report

15. 05. 97

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Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,  
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Authorized officer

Barton, S

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 96/17536

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR 1 466 248 A (BERSAC) 31 March 1967  see page 2, column 2, paragraph 2; figure 1  ---	4,5, 7-11,28, 29
A	US 5 368 597 A (PAGEDAS) 29 November 1994 see figure 3  ---	14
A	WO 94 08519 A (SHTURMAN) 28 April 1994 see figures 1-3  ---	14,32
A	EP 0 499 491 A (CARDIAC PATHWAYS) 19 August 1992 see figures 1,11  ---	14,32
A	EP 0 539 125 A (ETHICON) 28 April 1993 see figures 3-5  ---	14,32
A	US 5 487 385 A (AVITALL) 30 January 1996  ---	
A	DE 30 38 885 A (FRESENIUS) 27 May 1982 see figure 1  -----	4



## INTERNATIONAL SEARCH REPORT

national application No.

PCT/US 96/17536

**Box I** Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 12, 13, 19-26  
because they relate to subject matter not required to be searched by this Authority, namely:  
PCT Rule 39.1 (1v)
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II** Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Subject no.1: Claims 1-3, 27, 28, 33;  
Subject no.2: Claims 1, 4-6, 7-11 and 27, 28.2-30;  
Subject no.3: Claims 14-18, 27, 31, 32

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 96/17536

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9534346 A	21-12-95	EP 0765178 A	02-04-97
US 4850351 A	25-07-89	AU 604782 B	03-01-91
		AU 8096087 A	26-05-88
		CA 1303681 A	16-06-92
		DE 3739965 A	08-09-88
		FR 2606994 A	27-05-88
		GB 2198648 A,B	22-06-88
		JP 63212343 A	05-09-88
		NL 8702597 A	16-06-88
		AU 588272 B	14-09-89
		AU 5224486 A	27-11-86
		BR 8601969 A	06-01-87
		CA 1295374 A	04-02-92
		DE 3610270 A	27-11-86
		DE 3645125 A	31-08-89
		DE 3645161 A	08-03-90
		FR 2582220 A	28-11-86
		GB 2175505 A,B	03-12-86
		GB 2208805 A,B	19-04-89
		GB 2208806 A,B	19-04-89
		GB 2208807 A,B	19-04-89
		JP 61268245 A	27-11-86
		NL 8601292 A	16-12-86
US 5454370 A	03-10-95	NONE	
WO 9007909 A	26-07-90	AU 5098290 A	13-08-90
FR 1466248 A	31-03-67	NONE	
US 5368597 A	29-11-94	NONE	
WO 9408519 A	28-04-94	US 5312427 A	17-05-94
		AU 5167893 A	09-05-94
		US 5360432 A	01-11-94
EP 499491 A	19-08-92	US 5156151 A	20-10-92
		AU 662119 B	24-08-95
		AU 1088992 A	20-08-92

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 96/17536

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 499491 A		CA 2061219 A	16-08-92
		EP 0771547 A	07-05-97
		JP 7178113 A	18-07-95
		US 5345936 A	13-09-94
		US 5415166 A	16-05-95
		US 5406946 A	18-04-95
		US 5425364 A	20-06-95
		US 5456254 A	10-10-95
		US 5404638 A	11-04-95
		US 5465717 A	14-11-95
		US 5279299 A	18-01-94
		US 5228442 A	20-07-93
-----			
EP 539125 A	28-04-93	AT 139098 T	15-06-96
		AU 658932 B	04-05-95
		AU 2706692 A	22-04-93
		CA 2080766 A	19-04-93
		DE 69211480 D	18-07-96
		DE 69211480 T	07-11-96
		ES 2088109 T	01-08-96
		GR 92100466 A	30-06-93
		JP 5200122 A	10-08-93
		US 5358496 A	25-10-94
-----			
US 5487385 A	30-01-96	AU 1265495 A	19-06-95
		CA 2177982 A	08-06-95
		EP 0731665 A	18-09-96
		WO 9515115 A	08-06-95
-----			
DE 3038885 A	27-05-82	NONE	
-----			